IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA ex rel. SARAH BEHNKE,

Plaintiff,

Civil Action

No. 14-cv-824

v.

CVS CAREMARK CORPORATION et al.,

Defendants.

MEMORANDUM OPINION

GOLDBERG, J. March 25, 2024

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I. <u>INTRODUCTION</u>

Relator Sarah Behnke ("Relator") has brought this <u>qui tam</u> action under the False Claims Act, 31 U.S.C. § 3729, asserting the interests of the United States of America, against Defendants CVS Caremark Corporation and similarly named entities (collectively "Caremark"). The United States has declined to intervene. Relator alleges that Caremark caused certain health insurers to misrepresent to the government the amount they spent on prescription drugs purchased on behalf of Medicare beneficiaries. The details of the alleged fraudulent scheme are complicated, but the gist of Relator's claim is that Caremark, a pharmacy benefits manager (PBM), contracted with pharmacies to pay a fixed average price for drugs but actually reported individual sale prices that were higher.

Before me are Caremark's motion for summary judgment and Relator's motion for partial summary judgment. Caremark asserts that Relator is unable, as a matter of law, to prove her fraud claims, while Relator seeks a ruling that certain elements of her claims (falsity, materiality, and causation) have been established such that there is no material factual dispute.

There are essentially six primary points of disagreement between the parties, as follows: First, the parties dispute which price Caremark's clients were required to report—the average price or the individual sale price for a single prescription. Second, the parties dispute whether a negotiated average price existed between Caremark and one pharmacy (CVS). Third, assuming Relator is correct that the average price should have been reported, the parties dispute whether Caremark was sufficiently aware of this obligation to satisfy the scienter element of the False Claims Act. Fourth, it is disputed whether the alleged misrepresentations were material. Fifth, the parties dispute whether Caremark caused its clients make the alleged misrepresentations. And, lastly, the parties disagree on whether Relator can prove damages through an appropriate calculation.

For the reasons set out below, Caremark's motion for summary judgment will be denied, except as to one issue involving Caremark's payments to CVS in 2011 and 2012. Relator's motion for partial summary judgment will be granted only as to falsity and whether Caremark caused SilverScript's price submissions. Relator's motion will be denied in all other respects.

II. SUMMARY OF ISSUES IN DISPUTE

A. Required Reporting of Guaranteed Average Pricing

Medicare Part D is a federal government program that subsidizes the cost of prescription drugs for Medicare beneficiaries. To calculate appropriate subsidies, the government needs to know how much insurers, referred to as "Part D sponsors," spend on drugs. Accordingly, the Centers for Medicare and Medicaid Services (CMS), which oversees the Medicare Part D program, promulgated regulations requiring Part D sponsors to file certain reports detailing the cost of the drugs they purchased. Two of those Part D sponsors—Aetna and SilverScript—were clients of Caremark, with Caremark purchasing drugs on their behalf and providing information to Aetna and SilverScript that were used in their reports to CMS.

At the heart of the parties' dispute is what prices Aetna and SilverScript should have reported given the particular pricing arrangements Caremark had with pharmacies. Some of Caremark's pharmacy contracts gave Caremark flexibility to choose its own individual sale prices for purchased drugs, but also required Caremark to spend at least an aggregate, average amount on all drugs purchased throughout the year. The parties disagree as to which of those two prices, which I will refer to as the "individual sale price" and the "guaranteed average price," should have been reported to CMS. Relator contends that the guaranteed average price was the actual cost of drugs and therefore that amount should have been reported, whereas Caremark asserts that it only had to report the individual sale price. The parties agree that resolution of which of these two prices

should have been reported turns on the meaning of CMS's regulations. Both parties seek summary judgment in their favor on this issue.

B. Pricing Relationship Between Caremark and CVS

Although the parties agree that Caremark contracted with Walgreens and Rite Aid to pay a certain average price for drugs over the course of a year, the parties disagree as to whether Caremark made a similar commitment to CVS Pharmacy ("CVS"), which is in the same corporate family as Caremark. The parties agree that Caremark had an average price "target" with CVS, but disagree as to whether Caremark was required to meet this target.

Both parties seek summary judgment in their favor on this issue.

C. Allocation of Responsibilities Among Caremark and Its Clients

Although Relator has sued only Caremark, Caremark did not itself sponsor Medicare Part D insurance plans. Instead, the Part D sponsors involved in this case were Aetna and SilverScript. To prove her fraud claims, Relator must therefore demonstrate that Caremark "caused" Aetna and SilverScript to submit false reports. The parties dispute how much responsibility each of these actors—Caremark, Aetna, and SilverScript—had for ensuring the accuracy of reports. In Relator's view, Aetna and SilverScript were mostly unable to verify the accuracy of reported drug prices because they did not have access to Caremark's pricing information. Caremark disagrees.

Caremark has not sought summary judgment on the issue of whether it caused the submission of false claims. Relator seeks a partial summary judgment ruling in her favor on causation.

D. Sufficiency of Relator's Subsidy Calculations

Relator has produced an expert report that calculates how much CMS would have paid out in Medicare Part D subsidies to Aetna and SilverScript had prices been reported in the manner Relator says was required. The conclusion of Relator's expert's report is that had prices been properly reported, CMS would have paid a lower subsidy.

Caremark asserts that Relator's expert's analysis is insufficient to meet Relator's burden to prove damages. Caremark does not contend that Relator's expert made an error in calculation or that the hypothetical price reports used would have been inconsistent with CMS's regulations as Relator contends they should be interpreted. Rather, Caremark posits that Relator's expert's methodology does not demonstrate which individual drug prices were reported too high and instead shows at most that reported prices were too high in the aggregate. Caremark contends that this type of aggregate proof is improper under the False Claims Act because the Act requires a plaintiff to isolate specific "false claims," which Caremark reads to mean specific drug prices for individual purchases. Relator disagrees and insists that aggregate proof is appropriate, particularly given that CMS itself calculates subsidies and makes subsidy payments in the aggregate.

Caremark seeks summary judgment in its favor on this issue. Relator has not moved for summary judgment as to her subsidy calculations.¹

E. Materiality of Alleged Misstatements

Assuming Relator is correct about the prices Caremark's clients should have reported, the parties disagree as to whether the alleged deviations from those requirements were material. In support of materiality, Relator points to the fact that drug prices were used to calculate subsidies, that inflated prices led to inflated subsidies, and that CMS required Part D sponsors to certify the accuracy of reported prices as a condition of receiving subsidy payments.

Caremark responds that CMS became aware of how Caremark was reporting prices yet took no action in response, and thus CMS did not view any inaccuracy as material.

Both parties seeks summary judgment in their favor on this issue.

¹ Relator generally seeks summary judgment as to "causation," but her brief only addresses whether Caremark caused the submission of false claims, not whether those claims caused the government to overpay.

F. Scienter

The parties disagree as to whether Caremark was sufficiently aware of any errors in reported prices to meet the scienter element under the False Claims Act. As proof of scienter, Relator points to various Caremark internal documents, as well as communications between Caremark and Aetna that Relator claims show that Caremark understood the conflict between its conduct and CMS's regulations.

Caremark does not dispute that it was aware of certain basic facts: the nature of its pharmacy contracts, the prices its clients reported, and the content of CMS regulations setting the required price reporting. Instead, Caremark's argument on scienter is that, assuming Relator's interpretation of CMS's regulations to be correct, Caremark misunderstood them. Caremark points to statements from its experts that the way it reported prices was "industry standard." Caremark also notes interactions between itself and CMS that Caremark contends left it with the impression that CMS had blessed its price reporting practices.

Caremark seeks summary judgment in its favor on this issue. Relator has not moved for summary judgment as to scienter.

III. FACTS

A. Structure of Medicare Part D

The following facts and background regarding the structure of Medicare Part D are undisputed. 2

² Relator's assertion that some facts are "disputed as irrelevant" is improper and will be disregarded. See Fed. R. Civ. P. 56(c) (setting out the bases on which a fact may be disputed).

1. Purpose

Medicare is a federal government health insurance program for people who are over 65 years old or who have certain disabilities. (Relator's Facts³ ¶ 1.) The part of Medicare that deals with prescription drug coverage is called "Medicare Part D." Under Part D, the government does not directly purchase drugs for Medicare beneficiaries; instead, private insurers contract with the government for the right to sell insurance plans covering prescription drugs to Medicare beneficiaries. Those health insurance plans are referred to as "Part D plans," and the insurers who contract with the government to sell them are known as "Part D sponsors." A single Part D sponsor may offer many different Part D plans. The federal government agency in charge of Medicare Part D is the Centers for Medicare and Medicaid Services ("CMS"). (Caremark's Facts ¶¶ 45-49.)

Non-Medicare health insurance plans—called "commercial" plans—may also cover prescription drugs. A single insurance company may sell both Part D and commercial insurance plans. (See Caremark's Facts ¶ 76, 96.)

2. Insurers, Pharmacies, and PBMs

Individuals covered by an insurance plan ("members") typically purchase drugs from pharmacies, such as Walgreens or Rite Aid. Sometimes, a health insurer will delegate the task of establishing relationships with pharmacies to an intermediary entity called a "pharmacy benefits manager" ("PBM"), with the insurer being the PBM's "client." The PBM will enter into contracts with pharmacies in which the PBM promises to reimburse pharmacies for drugs purchased by

³ The parties statements of facts in support of their respective motions for summary judgment are referred to as "Relator's Facts" (ECF No. 282) and "Caremark's Facts" (ECF No. 275-2), and the responses thereto as "Caremark's Response to Relator's Facts" (ECF No. 295) and "Relator's Response to Caremark's Facts" (ECF No. 289-1). The parties' additional statements of facts offered in opposition to summary judgment are "Relator's Additional Facts" (ECF No. 289-2) and "Caremark's Additional Facts" (ECF No. 295).

members insured under the PBM's clients' health plans. Under a separate contract, the insurer reimburses the PBM for its services. (Caremark's Facts ¶¶ 10-13.) In this case, Caremark was the PBM for health insurers Aetna and Silverscript.

B. Medicare Part D Price Reporting and Subsidies

During the time period relevant to this case,⁴ the federal government subsidized a portion of the cost of providing prescription drugs to Medicare beneficiaries insured under Medicare Part D plans. Explaining the exact form of these subsidies is complicated. Generally, however, a subsidy can be understood as a reimbursement from CMS to cover a portion of the Part D sponsor's spending on prescription drugs. The government therefore had to determine how much Part D sponsors were spending on prescription drugs in order to calculate an appropriate subsidy for the sponsor's spending. Relator's fraud claims focus on the information Caremark supplied to its clients—Aetna and SilverScript—which Aetna and SilverScript subsequently reported to the government about how much they had spent on prescription drugs.

Where, as in this case, a Part D sponsor used the services of a PBM to establish a pharmacy network, the cost of drugs was measured by what the PBM paid the pharmacies, not what the Part D sponsor paid the PBM. (Caremark's Facts ¶ 257.) Thus, if the PBM earned margin or "spread" by charging its Part D sponsor client more than what it paid the pharmacy, the government would only subsidize what the PBM paid the pharmacy and would not subsidize the "spread." (See id.) For that reason, in the following discussion, references to spending by sponsors should be understood to include, where applicable, spending by the sponsor's PBM—that is, Caremark.

⁴ Many of the facts set out in this section remain true today. However, for clarity, and because some of the pertinent regulations have been amended, all facts are stated in the past tense.

A central issue in this case is how much Caremark actually spent on prescription drugs for Part D beneficiaries versus how much spending was reported by Caremark through Caremark's clients. Briefly summarized, Relator claims that an aggregate, average price negotiated between Caremark and certain pharmacies was the amount that Caremark actually spent and therefore is what Caremark's clients should have reported. Caremark disagrees, and asserts that a different, individual sale price was what it actually spent, even if the individual sale price differed from what Caremark had promised to pay the pharmacy in the aggregate.

The parties agree on which regulations applied to the conduct at issue in this case. However, as described later in this Opinion, the parties disagree as to how those regulations should be interpreted.

1. Regulatory Definitions of Drug Costs

To determine which prices reflected the actual cost of prescription drugs for Caremark and its clients, it is necessary to examine how CMS defined "cost." CMS's regulations defined two terms relevant to understanding what a Part D sponsor actually paid for prescription drugs: "gross covered prescription drug costs" and "actually paid" costs. The definitions of these terms are set out below, but, in short, "gross covered prescription drug costs" referred to the total amount the sponsor spent on drugs, including the cost of the drugs themselves and any other fees or sales tax charged by the pharmacy. "Actually paid" costs were costs that had been adjusted to account for transactions such as rebates that would reduce what it ultimately cost the sponsor to purchase drugs. Those adjustments were called "direct and indirect remuneration" ("DIR"). When it came to calculating the amount of Medicare Part D subsidies that the sponsor would receive, CMS's regulations specified that only "actually paid" costs would be used. See, e.g., 42 C.F.R. \$\\$ 423.329(c)(1) (effective March 13, 2009) (defining the reinsurance subsidy in terms of

"allowable reinsurance costs"), 423.308 (effective June 7, 2010) (defining "allowable reinsurance costs" in terms of amounts "actually paid").

(a) "Gross Covered Prescription Drug Costs"

CMS's regulations contained a lengthy definition of "gross covered prescription drug costs," but most of that definition was devoted to the nuances of how cost-sharing payments (such as copays) were to be counted—details that are immaterial for present purposes. The relevant portions of that definition were as follows:

Gross covered prescription drug costs mean those actually paid costs incurred under a Part D plan, excluding administrative costs, but including dispensing fees, during the coverage year. They equal the sum of the following:

- (1) The share of actual costs (as defined by § 423.100 of this part) actually paid by the Part D plan that is received as reimbursement by the pharmacy
- [(2)-(3) various cost-sharing payments].

42 C.F.R. § 423.308 (effective June 7, 2010). The phrase "excluding administrative costs" meant that the cost of PBM services was excluded, and it is not at issue in this litigation. "Dispensing fees" are also not at issue. Rather, the important phrase is "[t]he share of <u>actual costs</u> ... <u>actually paid</u> by the Part D plan that is received as reimbursement by the pharmacy." § 423.308 (emphasis added). The referenced term "actual cost" was defined, in relevant part, as:

Actual cost means the negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy

42 C.F.R. § 423.100 (effective June 7, 2010). All pharmacies at issue in this case were "network pharmacies." The phrase "negotiated price" was defined as:

Negotiated prices means prices for covered Part D drugs that—

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug;

- (2) Are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and
- (3) Includes any dispensing fees.

42 C.F.R. § 423.100 (effective June 7, 2010).

(b) "Actually Paid" Costs and Direct and Indirect Remuneration (DIR)

As noted, the subsidies to which a Part D sponsor was entitled depended only on the subset of its drug spending that was "actually paid." That term was defined as:

Actually paid means that the costs must be <u>actually incurred</u> by the Part D sponsor and must be <u>net of any direct or indirect remuneration</u> (including discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers) from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred under the Part D plan. ...

42 C.F.R. § 423.308 (effective June 7, 2010) (emphasis added).

That same paragraph proceeded to describe the types of transactions that could reduce the cost of purchasing drugs, using a nonexclusive list:

Direct and indirect remuneration includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies or similar entities obtained by an intermediary contracting organization with which the Part D plan sponsor has contracted, regardless of whether the intermediary contracting organization retains all or a portion of the direct and indirect remuneration or passes the entire direct and indirect remuneration to the Part D plan sponsor and regardless of the terms of the contract between the plan sponsor and the intermediary contracting organization.

Id.

For example, if a Part D sponsor paid the pharmacy \$5 for a drug but received a \$2 rebate from the manufacturer, the \$2 would be considered DIR, and the actual cost of the drug would be \$3. Similarly, if the pharmaceutical manufacturer offered "administrative services" to the Part D

sponsor at a discount, that discount would be considered DIR even though it was a discount on services rather than on the drugs themselves. (See Caremark's Ex. 56, "Final Medicare Part D DIR Reporting Requirements for 2010 Payment Reconciliation: Summary Report," pp. 7-8.)

Viewing the above definitions of "gross covered prescription drug costs," "actual cost," and "actually paid" together, the drug costs that counted for purposes of Medicare Part D subsidies were those that: (1) were the "negotiated prices" between the sponsor (or PBM) and the pharmacy; (2) were "actually incurred"; and (3) were net of DIR.

2. Reporting of Drug Spending

Because Medicare Part D subsidies depended, in part, on what plan sponsors (and their PBMs) "actually paid" for prescription drugs, CMS developed a system for plan sponsors to report what those payments were. As described in more detail below, CMS's rules required sponsors to submit two separate types of reports that, combined, would produce the correct total drug spending: (1) prescription drug event (PDE) records, which gave the prices for individual purchases (i.e., one filled prescription for one plan member); and (2) direct and indirect remuneration (DIR) reports, which included all other discounts and rebates that affected what it cost the Part D sponsor (or its PBM) to purchase those drugs. These two types of reports are described below. (These facts are undisputed.)

(a) <u>Prescription Drug Event (PDE) Records</u>

Part D sponsors were required submit prescription drug event (PDE) records for each drug purchased by a plan member. (Caremark's Facts ¶ 223.) The information to be included in PDE records was set out in CMS publications titled "Updated Instructions: Requirements for Submitting Prescription Drug Event Data (PDE)" (hereinafter 2006 PDE Instructions) and "Prescription Drug Event Participation Guide" (hereinafter 2011 PDE Guide). (Caremark's Exs. 7, 55; Caremark's

Facts ¶¶ 224, 229.)⁵ In particular, each PDE record contained information about the price of the drug purchased. Although the reported price was broken down into three components, this breakdown is unimportant to Relator's fraud claims, and only the total price is relevant. CMS's documents described the drug cost in the PDE record as the "gross covered drug cost" or "gross covered prescription drug cost" for the sale, and stated that this price corresponded to the term "gross covered prescription drug costs" as defined in the regulation. See 42 C.F.R. § 423.308. Each PDE record also contained information about how much of the drug cost CMS was required to subsidize. (Norwalk Opening Report ¶¶ 74-75; Caremark's Ex. 55, 2011 PDE Guide § 1.2.2.1, § 3.3.3.5 at p. 3-16, § 3.4, § 5.1 at p. 5-2.)

(b) Direct and Indirect Remuneration (DIR) Reports

As noted above, the amount a Part D sponsor "actually paid" for drugs had to be adjusted to account for transactions such as rebates—called "direct and indirect remuneration" or DIR—that tended to reduce the cost of purchasing drugs. For example, if the Part D sponsor paid \$5 for the drug but received a \$2 rebate, the "gross covered prescription drug cost" for that purchase would be \$3, not \$5, because the \$2 would be DIR.

However, CMS did not require that the prices contained in PDE records be adjusted to account for <u>all</u> price concessions that affected the cost of drugs, only "[point of sale] price concessions." Instead, any price concessions "not reflected in the cost of the drug on the PDE record" had to be included in another type of report: a "DIR report." (<u>See</u> Caremark's Ex. 55, 2011 PDE Guide, §§ 1.2.2, 1.5.2.2; Caremark's Ex. 57, "Final Medicare Part D DIR Reporting Requirements for 2011," hereinafter "2011 DIR Reporting Requirements."⁶)

⁵ Neither party has identified any relevant variation among different versions of these documents.

⁶ Although the parties' experts cite to multiple versions of this document, the parties' briefing does not mention any relevant variation among them.

Part D sponsors were required to submit a DIR report after the end of the year containing information about transactions that occurred during the year that reduced the cost of drugs. Thus, unlike with the PDE records described above, Part D sponsors were not required to submit a separate DIR report for every individual drug purchase. Rather, end-of-year DIR reports would aggregate rebates and price adjustments received throughout the year that reduced the cost to the Part D sponsor of purchasing drugs. (See Caremark's Ex. 57, 2011 DIR Reporting Requirements, § II.A at pp. 9, 23, § E at p. 23; Norwalk Opening Report ¶ 81; Caremark's Facts ¶ 234.)

3. Subsidies

Medicare Part D is a federally subsidized program. During the relevant time period, applicable regulations provided for the federal government to pay multiple types of subsidies to Part D plan sponsors. See 42 C.F.R. § 423.315 (effective March 22, 2005). This Opinion discusses only the three types of subsidy payments that Relator claims were affected by Caremark's allegedly false price reporting: (1) the "reinsurance" subsidy; (2) the "low-income cost sharing" ("LICS") subsidy; and (3) "risk-corridor" payments. (See Smith Amended Opening Report ¶ 87 (describing damages calculation).) (The parties do not dispute the facts set out below regarding how these subsidies were calculated and paid.⁷)

(a) Reinsurance Subsidy

Through the reinsurance subsidy, the federal government would pay 80% of the cost of prescription drugs for a Part D plan member once the spending for that member exceeded the

⁷ Caremark's expert Leslie Norwalk categorizes these subsidies slightly differently in that she includes year-end adjustments to the reinsurance and LICS subsidies under the heading of risk corridor payments. (See Norwalk Opening Report ¶ 66.) However, the experts agree on the mechanics of how these subsidies were calculated, and the difference in terminology is immaterial to the issues addressed in this Opinion.

threshold for "catastrophic" coverage for that year. 42 C.F.R. § 423.329(c)(1) (effective March 22, 2005). (Norwalk Opening Report⁸ ¶¶ 59-60.)

By regulation, CMS could either issue a reinsurance subsidy each month based on that month's actual spending or issue an estimated subsidy and then "reconcile" (i.e., correct) that estimate after the year's end. See 42 C.F.R. § 423.329(c)(2) (effective March 13, 2009). The parties agree that during the years at issue in this case, CMS used the latter method. (See Norwalk Opening Report ¶ 61; Smith Amended Opening Report ¶ 43.) However, the difference between these two methods is not material to the issues addressed in this Opinion because the end result was the same: CMS ultimately paid a reinsurance subsidy based on the actual amount each Part D plan spent on prescription drugs for each member during the year. See 42 C.F.R. § 423.343(c) (effective March 22, 2005).

It is important to note that the reinsurance subsidy was calculated on a member-by-member basis. Thus, if a plan member's drug spending for the year did not cross the catastrophic threshold, the plan sponsor would receive no reinsurance subsidy corresponding to that member for that year, even if other members were above the catastrophic threshold. (See Norwalk Opening Report ¶ 66.b.) By way of example, suppose the catastrophic threshold for two members was \$1,000. If each member spent \$800 during the year, CMS would pay no reinsurance subsidy for these members. But if one member spent \$1,600 and the other \$0, CMS would subsidize the \$600 in excess of the \$1,000 threshold. Thus, even though the total spending would be the same between these

⁸ The expert reports cited in this Opinion are Norwalk Opening Report (Caremark's Ex. 6), Smith Amended Opening Report (Caremark's Ex. 52), Craft Second Amended Opening Report (Caremark's Ex. 109), and Barlag Amended Rebuttal Report (Caremark's Ex. 50).

⁹ It should be noted that this case involves two unrelated transactions termed "reconciliations": reconciliations between Part D sponsors and CMS (as described here), and reconciliations between Caremark and its contracted pharmacies (discussed later in connection with Caremark's business).

two scenarios—i.e., \$1,600—the subsidy payments would be different because the per-member spending would be different.

However, Part D sponsors did not report all spending on a member-by-member basis, because the price concessions included in DIR reports were aggregated throughout the year and did not reflect individual purchases. To make up for this discrepancy, CMS would attribute a portion of DIR to the plan's reinsurance subsidy using a formula. Consequently, if the Part D sponsor reported that it had received price concessions not reflected in the individual sale prices it had reported in PDE records, the plan's reinsurance subsidy would be reduced by a calculated amount. (See Caremark's Ex. 57, 2011 DIR Reporting Requirements; Norwalk Opening Report ¶¶ 87-88; Caremark's Ex. 55, 2011 PDE Guide § 1.6.3.4.)

(b) <u>Low-Income Cost Sharing (LICS) Subsidy</u>

The low-income cost sharing (LICS) subsidy applied to Part D plan members who qualified based on their income and other resources. (See Craft Second Amended Opening Report ¶ 69; Norwalk Opening Report ¶ 55.) For qualifying members, the government would cover some or all of the members' deductibles and copayments. 42 C.F.R. § 423.782 (effective June 6, 2011).

As with the reinsurance subsidy, the LICS subsidy was calculated on a member-by-member basis because it only applied to qualifying members. However, unlike with the reinsurance subsidy, DIR was not factored into the calculation of the LICS subsidy, and there was accordingly no need to allocate any portion of DIR to the LICS subsidy. (See Caremark's Ex. 55, 2011 PDE Guide §§ 1.6.2.2, 1.6.2.3.2.)

(c) Risk Corridor Payments

CMS used risk corridor payments to limit the aggregate amount of gain or loss a Part D plan could incur throughout the year. (See Norwalk Opening Report ¶ 67; Craft Second Amended Opening Report ¶ 73.) At the end of the year, CMS would calculate the gain or loss by comparing

the total amount the plan spent on prescription drugs (adjusted for any reinsurance or LICS subsidies received) to its predicted expenditure. 42 C.F.R. §§ 423.336(a) (effective March 22, 2005); 423.308 (effective June 7, 2010). Spending in excess of the prediction was a loss; spending below the prediction was a gain. If the magnitude of the gain or loss was less than a certain amount (called the "first threshold"), the plan would bear the entire risk and no adjustments would be made. 42 C.F.R. § 423.336(b)(1). If, on the other hand, the magnitude of the gain or loss exceeded the threshold, the government would share a portion of it. Thus, if the plan made a gain over the threshold, the plan would be obligated to return some of that gain to the government, and if the plan suffered a loss above the threshold, the government would repay the plan for a portion of that loss. <u>Id.</u>

Note that unlike the reinsurance and LICS subsidies, risk corridor payments operated on the plan as a whole rather than on a member-by-member basis. See § 423.336(a). But because each Part D sponsor could have multiple Part D plans, it was still necessary to allocate reportable price concessions received by the sponsor among its various plans to calculate the appropriate risk corridor payments. (See Caremark's Ex. 57, 2011 DIR Reporting Requirements, p. 9; Caremark's Ex. 55, 2011 PDE Guide § 1.6.4.)

4. Reporting as a Condition of Payment

To receive the subsidies described above, Part D plan sponsors were required to submit "such information as may be required" for the Secretary of Health and Human Services to carry out certain statutory requirements, and to do so "in a form and manner specified by the Secretary." (Relator's Facts ¶ 197 (citing 42 U.S.C. § 1395w-115(d)(2)(A)).) The statutory subsection conditioning payment on reporting did not expressly reference any specific type of report (such as PDE records or DIR reports) or specific items of information in those reports.

CMS further required Part D sponsors and their PBMs to certify to the accuracy of reported data and to acknowledge that the data would be used "for the purpose of obtaining Federal

reimbursement." (Relator's Facts ¶ 198.) Caremark characterizes this certification as "boilerplate." (Caremark's Response to Relator's Facts ¶ 198.) In a document titled "Prescription Drug Benefit Manual," CMS wrote that submitting "inaccurate or incomplete prescription drug event (PDE) data" or "fail[ing] to disclose or misrepresent[ing] rebates, discounts, price concessions, or other value added gifts" would be examples of fraud. (Relator's Ex. 197 at 54-57.)

5. Payment Reconciliation System

As noted above, CMS would make estimated payments throughout the year for certain subsidies and then "reconcile" (correct) those payments after the end of the year through a process known as the "Payment Reconciliation System." The parties agree that CMS would make these reconciliation payments "in the aggregate," which I understand to mean as a single payment covering all subsidies rather than separate payments for each individual PDE record submitted throughout the year. (Relator's Facts ¶ 12 and Caremark's response thereto.)

C. Caremark's Business

During the relevant period, Caremark provided PBM services to various health insurers, including Aetna and SilverScript, both Part D sponsors. Aetna also offered commercial (i.e. non-Medicare) prescription drug plans. Under those arrangements, Caremark would pay for drugs purchased at pharmacies by members of Aetna's and SilverScript's health plans, and Aetna and SilverScript would pay Caremark for those services. (Caremark's Facts ¶¶ 13, 95-99, 100, 106, 112.)

Relator asserts claims only for certain combinations of Part D sponsors, pharmacies, and years. (See Relator's Facts ¶ 46 n.1.) The sections below discuss only the facts relevant to the combinations underlying Relator's claims.

D. Caremark's Pharmacy Contracts

At issue in this case is how Caremark (through its clients) reported prices it paid three pharmacies: Walgreens, Rite Aid, and CVS Pharmacy ("CVS"), ¹⁰ all of which are large, nationwide retail pharmacy chains. (Caremark's Facts ¶ 117.) Relator's allegation, briefly summarized, is that Caremark reported a price that was higher than the one Caremark had contracted with the pharmacies to pay. It is therefore necessary to examine Caremark's contracts with these three pharmacies.

1. Walgreens and Rite Aid

Caremark's contracts with Walgreens and Rite Aid were essentially the same for present purposes, and as such this section focuses on Walgreens. (See Caremark's Facts ¶¶ 130-31, 135, 182, 194.) Caremark's contracts with Walgreens contained two sets of provisions on pricing that are relevant to this lawsuit.

(a) <u>Pricing of Individual Drug Purchases</u>

The first relevant set of provisions was a section titled "Reimbursement to Provider," which set out the rates at which Walgreens would be reimbursed for individual drug purchases. (Caremark's Ex. 26, § 4.3, at CVS-BEHNKE-0001202.) Those rates were set according to formulas that varied depending on which pharmacy network the associated health plan participated in. These

¹⁰ CVS is in the same corporate family as Caremark, and Defendants include entities with names such as "CVS Caremark Corporation." For clarity, this Opinion refers to the PBM side of the business as "Caremark" and the pharmacy side of the business as "CVS." The parties strenuously contest the relationship between the PBM and pharmacy sides of the business, as explained in more detail below.

¹¹ Some documents in the summary judgment record refer to the price paid on an individual purchase as the "point-of-sale price." For clarity, this Opinion uses the term "individual sale price." The parties also refer to individual purchases as "claims" because that is the term for the reimbursement request sent by the pharmacy to Caremark. However, because the word "claim" has multiple meanings in this lawsuit, and because the mechanics of how the pharmacy requested payment are immaterial to any issue in dispute, this Opinion will use the term "purchases."

formulas used a "lower of" system in which multiple possible rates were specified and Walgreens would receive whichever of those rates turned out to be lowest for that purchase. (Caremark's Facts ¶¶ 28-29, 121.) For example, in the case of "PCS National Networks," Walgreens would receive the "lower of":

- (i) "AWP [average wholesale price] less the applicable Discount (as defined in the Enrollment Form) plus the applicable Dispensing Fee (as defined in the Enrollment Form) less the applicable Copay";
- (ii) "MAC [maximum allowable cost] plus the applicable Dispensing Fee less the applicable Copay";
- (iii) "Ingredient Cost submitted by Provider plus the applicable Dispensing Fee less the applicable Copay"; or
- (iv) "Usual and Customary Price less the applicable Copay." (Caremark's Ex. 26, § 4.3.1, at CVS-BEHNKE-0001202.)

One of those terms warrants special attention: the maximum allowable cost or "MAC" price. A MAC price was a per-unit price that Caremark would set for some drugs, typically multisource generic drugs. Caremark had discretion to decide what its MAC prices would be. (Caremark's Facts ¶ 33-34, 37, 122.) According to the "lower of" formula, if Caremark had set a MAC price for the purchased drug, and the MAC price happened to be lower than the other three items (discounted average wholesale price, ingredient cost, or usual and customary price), Walgreens would receive Caremark's MAC price for that purchase. (See Caremark's Facts ¶ 29.) The parties briefing does not disclose how often the MAC price would be the lowest price, but the parties generally assume that the MAC price was often the lowest price such that changing MAC prices could significantly impact how much Caremark paid on average. (See ECF No. 304 at 4 ("The MAC price typically was the 'lowest of' the applicable metrics for generic drugs").)

¹² The "copay" is a portion of the cost of the drug paid by the member and is not relevant to the issues discussed in this Opinion. As far as the parties' briefing reveals, the "dispensing fee" is also irrelevant.

What is important for this case is that Caremark could use its MAC lists to pay different prices for Medicare beneficiaries than for non-Medicare beneficiaries. That is because Caremark could use a different MAC price depending on which health plan the purchasing member belonged to. In particular, if the purchase was for a Medicare Part D plan from Aetna or Silverscript, Caremark would use a MAC price from a list that corresponded to that health plan, and bill the plan the same amount it paid the pharmacy. For non-Part D purchases, Caremark could use a different MAC list and bill the plan more than it paid the pharmacy. (See Caremark's Facts ¶ 43-44, 69, 261; Caremark's Additional Facts ¶¶ 40-42.) Thus, different prices could be paid depending on whether the purchase was for a Medicare beneficiary.

(b) Guaranteed Average Pricing

Caremark's contracts with Walgreens also contained provisions that ensured Walgreens would receive a certain level of reimbursement in the aggregate across different categories of purchases. These provisions were phrased using a calculation called a "generic effective rate" or "GER," but the exact mechanics of how a GER was calculated are unimportant to the issues in this case. What is important is that, in essence, Caremark promised to pay Walgreens at least an agreed-upon average price for drugs over the course of a year. (See Caremark's Facts ¶¶ 148-49, 152, 154-55, 182, 185, 189.)¹³

These contractual terms operated as a price floor but not a price ceiling: Caremark promised to pay at least the agreed-upon average, but could pay more. Thus, for example, if the promised average was \$10 and Caremark paid \$12, Walgreens would have no obligation to return the

¹³ Caremark's promise to the pharmacy was slightly more complicated than a promise to pay a single average price, because it was phrased in terms of drugs' average wholesale prices (AWP). (See Caremark's Facts ¶¶ 148-49.) Average wholesale prices were published industry-wide prices that were different for each drug, so there was not a single promised average price. However, this complication is not relevant to any issues addressed in this Opinion.

extra \$2. But, if Caremark paid less than the agreed-upon average, Caremark would have to make an end-of-year payment (called a "reconciliation" payment) to make up the difference. (See Caremark's Facts ¶ 152, 154-55, 187-88; Caremark's Ex. 49, Caremark's Answers to Interrogatories, at 12.) Relator's fraud claims in this case only pertain to pharmacies and years in which Caremark ended up having to make a reconciliation payment because its individual sale payments fell short of the promised average. Thus, in those years, Caremark ultimately paid the pharmacy exactly the promised average, no more and no less, once the reconciliation payment was accounted for.¹⁴

Central to Relator's fraud claims is the fact that in some contracts, Caremark and Walgreens agreed to an average price that encompassed both purchases for Part D plans and purchases for commercial plans—what the parties call an "overall" guarantee. Thus, for example, if Caremark promised to pay an average of at least \$10, Caremark could meet this obligation by paying \$12 on a purchase for a Part D member and \$8 on a purchase for a commercial member. Relator's claims only relate to pharmacies and years for which the average pricing guarantees encompassed both commercial and Part D purchases, and the remainder of this Opinion therefore does not discuss pharmacies and years for which average pricing guarantees applied separately to commercial and Part D purchases. It is undisputed that the average pricing guarantees for Walgreens and Rite Aid were "overall" for the pharmacies and years underlying Relator's claims. (See Caremark's Facts ¶¶ 186, 190-92, 212, 436; Caremark's Response to Relator's Facts ¶ 127.)

¹⁴ In reading the discovery materials, it is important to be aware that because the average pricing term was phrased as a discount, i.e., a reduction, from the drugs' average wholesale prices, documents sometimes refer to it as a "cap" or a "ceiling," but these terms should not be read to suggest that there was a cap on Caremark's <u>payments</u> to the pharmacy. Rather, a ceiling on the discount is a floor on the price.

¹⁵ With the caveat that the exact numbers would depend on the drug's average wholesale price.

As described in more detail later in this Opinion, Relator's fraud claims are based on the fact that the more Caremark paid on Part D purchases to Walgreens, the less it had to pay on commercial purchases to Walgreens in order to meet the promised average. (See Gugliuzza 6/10/22 at 81:2-17; Relator's Ex. 126, Caremark's Supplemental Response to Interrogatory No. 5.) That is because of how averages work: just as the average of 5 and 15 is 10, the average of 8 and 12 is also 10. So, increasing one contribution to the average allows others to decrease while keeping the average the same.

2. CVS

Unlike Walgreens and Rite Aid, CVS was in the same corporate family as Caremark. Also unlike with Walgreens and Rite Aid, the parties vigorously dispute Caremark's pricing relationship with CVS.

(a) Nature of Pricing Relationship

The parties first dispute whether Caremark and CVS had a negotiated average price, the way Caremark did with Walgreens and Rite Aid. It is undisputed that Caremark had a contract with CVS that set the per-transaction price for individual drug purchases. As with Walgreens and Rite Aid, CVS agreed to accept the "lower of" various prices, one of which was Caremark's chosen MAC price. It is also undisputed that unlike with Walgreens and Rite Aid, Caremark's formal, written contracts with CVS did <u>not</u> contain a term requiring Caremark to pay a certain average price for drugs. (See Caremark's Facts ¶¶ 136-37, 139-40, 144-45, 183.)

Instead, Caremark and CVS had what the parties refer to as a "budgeted" or "targeted" average price¹⁶ for some years.¹⁷ (See Caremark's Facts ¶ 145.) This targeted average price encompassed both commercial and Medicare Part D purchases—i.e., it was an "overall" average. (Boratto 10/7/22 at 26:24-27:5.) CVS in-house attorney Kevin Blake testified that calculating how much Caremark had over- or under-shot its targeted average with CVS would work similarly to how that result would be calculated for Walgreens or Rite Aid. (Blake 8/18/22 at 103:2-24.)

Although the parties agree that Caremark had a "targeted" average price with CVS, the parties disagree as to whether Caremark and CVS "negotiated" this average price. Whether there was a "negotiation" is potentially significant given that CMS regulations referred to the "negotiated price" between the Part D sponsor (or its PBM) and the pharmacy. See 42 C.F.R. § 423.100 (effective June 7, 2010). Caremark's then-Corporate Controller Eva Boratto testified that the budgeted average price between Caremark and CVS was set at a "meeting" between Caremark and CVS. According to Boratto, Caremark and CVS would each come to this meeting with a "point of view" about what the average price should be, and the outcome of the meeting would be a number for the average price. (Boratto 10/7/22 at 19:2-23.) However, Boratto also said that she "wouldn't call it a negotiated" average price, and instead testified that the aim in setting the average price was to achieve the goals of the "total company" or "total enterprise"—i.e., CVS and Caremark collectively. Boratto also testified that Caremark and CVS were "one company." (Id. at 19:17-23, 26:6-12.)

¹⁶ As with Walgreens and Rite Aid, this targeted average was based on average wholesale prices (AWP) and calculated as a generic effective rate (GER), but this detail is not important to understanding Relator's fraud claims.

¹⁷ The parties dispute whether there was a "budgeted" average price in 2010 through 2012, but agree on 2013 through 2016. (See Caremark's Facts ¶ 203 and Relator's response thereto.)

By contrast, former Caremark employee Domenico Gugliuzza testified that Caremark and CVS "agreed" on an average price, which they "negotiated." (Gugliuzza 6/10/22 at 21:16-20, 220:11-19.) An internal Caremark slide described Caremark's average price with CVS as an "agreement[]." (Relator's Ex. 83, CVS-BEHNKE-0180214, at -216.) Another referred to it as a "deal[]." (Relator's Ex. 184, CVS-BEHNKE-0010210, at -231.) In an internal email, Caremark employee Leroy Pruitt wrote that "CVS Pharmacy operates like any other contracted pharmacy in network" in that "[t]here is a firewall between PBM & CVS Retail," so the PBM side (i.e. Caremark) was "not able to dictate pricing to CVS Retail" and "[p]ricing is strictly based on contracted rates." (Relator's Ex. 87, CVS-BEHNKE-0208088, at -095.)

The parties also disagree on the extent of Caremark's obligation to adhere to the targeted average price: Relator views the target as obligatory, whereas Caremark insists it was free to disregard the target at its option. Caremark's Gugliuzza testified that Caremark treated its budgeted average price with CVS as a "cap," which is also how it treated its contracted average prices with Rite Aid and CVS, and agreed that the two were not "different, in all practical purposes." (Gugliuzza 6/10/22 at 21:11-22:1.)¹⁸ An internal Caremark presentation also stated that Caremark was "committed" to these rates. (Relator's Ex. 190, CVS-BEHNKE-0276683 at slide 2.) Gugliuzza also referred to the targeted average as a "commitment[]." (Gugliuzza 6/10/22 at 21:11-20.) Consistent with Gugliuzza's testimony, Caremark internal documents sometimes tabulated Caremark's pricing targets with CVS alongside its pricing guarantees with Rite Aid and Walgreens, without distinguishing among them. (E.g., Relator's Ex. 7, CVS-BEHNKE-0010125, at -128 to -130.) In an internal Caremark email, Caremark employee John Lavin stated that Caremark's individual sale prices with CVS could be "wherever you want" so long as Caremark met the targeted average.

¹⁸ Recall that a "cap" on the discount was a floor on the price. (See supra note 14.)

(Relator's Ex. 318.) By contrast, CVS in-house attorney Kevin Blake described the average pricing target between Caremark and CVS as a "target." (Blake 8/18/22 at 87:15-88:2.)

Relator has not come forward with evidence that Caremark would make reconciliation payments to CVS. That is, as far as the summary judgment record reveals, if, at year's end, Caremark had paid CVS less than the targeted average, Caremark would not make up the difference. (See Norwalk Opening Report ¶ 151.) There is testimony, from Caremark employee John Lavin, that Caremark "managed" the average through adjusting individual sale prices, which is discussed in more detail below. (See Lavin 5/6/22 at 131:5-14.)

(b) Rates for 2013 through 2016

While the parties agree that Caremark and CVS had targeted average prices from 2013 through 2016, they disagree as to whether Relator has pointed to sufficient evidence of what those targets were.

For each year of 2013 through 2016, Relator identifies spreadsheets that she calls "CVS Pharmacy Reconciliation Look-Alikes" in which numbers appear under headings for "CVS," "Gen Eff Rate," and "Overall." (See Relator's Ex. 106 (79.82%), Ex. 115 (81.16%), Ex. 116 (83.35%), Ex. 117 (84.09%).) CVS in-house attorney Kevin Blake testified that these spreadsheets tracked the "variance" between Caremark's budgeted target with CVS and actual performance. (See Blake 8/18/22 at 103-06.) For 2013, Relator also has a statement in an internal Caremark presentation that "CVS was set to committed rate of 79.8% for 2013 & 1.0% / year thereafter," which matches (approximately) the number from the spreadsheet. (Relator's Ex. 190, CVS-BEHNKE-0276683 at slide 2.) For 2014 through 2016, Relator does not have any document explicitly making the assertion that the rates in the spreadsheets were the rates agreed between Caremark and CVS.

Caremark responds that these spreadsheets are "only four out of hundreds" of similar documents "produced in this litigation." (Caremark's Response to Relator's Facts ¶ 124.) Caremark's

Expert Brett Barlag also objects that the spreadsheets Relator relies on contain rates that vary month-to-month (although it is unclear whether Barlag means that the "Overall" "Gen Eff Rate" that Relator chooses as the rate varies month-to-month). (Barlag Amended Rebuttal Report ¶ 65.) Caremark does not identify alternative targets, but insists that Relator has failed to offer sufficient evidence to support her proposed targets. (See Caremark's Response to Relator's Facts ¶ 125.)

(c) 2011 through 2012

The parties dispute whether Caremark and CVS had a "targeted" average price for 2011 through 2012.¹⁹

Relator's support that a target existed in 2011 and 2012 consists, in large part, of a single sentence from the deposition testimony of Caremark's Eva Boratto that a target was in effect from "2011 to 2016." (Boratto 10/7/22 at 26:24-27:11.) This testimony comes with the caveat that Boratto did not agree that the target was negotiated or that it was binding on Caremark. Relator also refers to a spreadsheet that appears to contain dollar amounts for something that happened in 2011, although it is unclear how the spreadsheet supports the assertion that Caremark and CVS had a targeted average price. (Relator's Ex. 107.) Relator's damages expert states that this spreadsheet contains "internal forecasts" and that he used it to "calculate a weighted average Pharmacy GER across all lines of business," a sentence that Relator's briefing does not explain further. (Smith Amended Opening Report ¶ 103.)

Caremark responds with testimony from CVS in-house attorney Stacey Bernstein that "between 2010 and 2012, there were negotiations between CVS Pharmacy and Caremark, but there wasn't necessarily any alignment on what the targeted budget numbers would be," meaning "there

¹⁹ The parties also disagree as to whether there was a target in 2010, but Relator is not seeking damages for 2010, and this Opinion therefore does not discuss 2010.

was no determination that the CVS number needed to align with the Caremark number." (Bernstein 10/20/22 at 35:23-36:10.) Caremark's expert Brett Barlag objects to Relator's damages expert using projected numbers for 2011 and 2012 because the numbers actually paid indicate a different rate. (Barlag Amended Rebuttal Report ¶ 65.)

E. How Caremark Set Individual Sale Prices

As described above, Caremark's individual sale prices to pharmacies were based, in substantial part, on "maximum allowable cost" or "MAC" prices that Caremark itself set. Part of Relator's fraud claims is an allegation that Caremark generally set individual sale prices for Part D purchases higher than for commercial purchases, while setting both to meet its average pricing commitment to the pharmacy. In Relator's view, each higher-than-average Part D payment enabled Caremark to make a lower-than-average commercial payment while still meeting the promised average, amounting to a discount or price concession that should have been reported. This section describes generally how Caremark set individual sale prices. The parties agree on the broad outline of these facts but disagree on the specifics, as discussed below.

The parties agree that, in setting individual sale prices, one of Caremark's goals was that, at year's end, the average of Caremark's individual sale payments would be close to the average price that Caremark had negotiated with the pharmacy. (Caremark's Facts ¶¶ 263-64; Boratto 10/7/22 at 56:22-57-18.) An example may help to illustrate how this process worked. Suppose Caremark and the pharmacy agreed that Caremark would pay an average of \$10 across all purchases. If Caremark made individual payments of \$6 and \$10, this would be an average of \$8, and Caremark would have to make up the \$4 shortfall (i.e., \$2 × 2) in an end-of-year payment. On the other hand, if Caremark made individual payments of \$6 and \$12, Caremark would be closer to

²⁰ With the caveat that the parties dispute the nature of Caremark's commitment to CVS.

the promised average and only a \$2 end-of-year payment (i.e., $$1 \times 2$)$ would be required. The parties agree that Caremark generally tried to achieve the second outcome: set individual sale prices so that their average was close to the target and only a small end-of-year payment was required. Note that no <u>individual</u> sale price had to be close to the promised average to achieve this goal—for example, individual sale prices of \$2 and \$18 would not individually be close to \$10, but they would average exactly \$10, thus achieving Caremark's goal.²¹

One point of disagreement between the parties is whether Caremark set individual sale prices solely to meet average price guarantees (or, in the case of CVS, the average price target), or whether Caremark took into account other factors as well. (See Caremark's Response to Relator's Facts ¶ 144, 147.) Caremark contends that in setting individual sale prices it "considered various factors, including marketplace dynamics, product availability, [and] different pricing sources." (Caremark's Facts ¶ 262; Kinney 5/10/22 at 118:14-119-:1.) Relator does not offer evidence that Caremark considered average pricing targets to the exclusion of all other factors, but does offer evidence, through its expert's report, that, regardless of what other factors Caremark might have considered, it succeeded in closely hitting the average pricing targets. (Smith Amended Opening Report ¶ 46; Relator's Facts ¶ 135.) For example, according to Dr. Smith's calculations, in 2013, Caremark missed the alleged CVS target by about \$4.5 million out of a total of about \$4.2 billion spent.

What is important for this case, however, is that Caremark did not adjust <u>all</u> individual sale prices to meet its guarantees to pharmacies. Instead, Caremark adjusted individual sale prices for Part D plans to meet other targets (involving Caremark's pricing guarantees to plan sponsors). (<u>See</u>

²¹ In practice, all of these numbers had to account for drugs' average wholesale prices (AWP), but this complication is immaterial to the issues discussed in this Opinion.

Caremark's Facts ¶¶ 265, 267.) Because of how averages work, Caremark could, at least in theory, accomplish both goals simultaneously: price all pharmacy purchases to meet commitments to pharmacies, but price the overlapping set of Part D purchases to meet commitments to Part D sponsors. (Caremark's Facts ¶ 268; Caremark's Response to Relator's Facts ¶ 144.) Thus, although the average of Caremark's individual sale prices would be close to Caremark's negotiated averages with pharmacies, the individual sale prices themselves could differ from the negotiated averages, and, in particular, could differ depending on which plan the drugs were purchased for—Part D or commercial. This spread between the average Part D price and the average overall price is at the heart of Relator's fraud claims.

An internal Caremark document that Relator refers to as a "reconciliation" workbook illustrates this concept. For Rite Aid in 2013, Caremark paid an average price of AWP-80.443%²³ on commercial purchases but a higher average price of AWP-76.046% on Part D purchases. (Relator's Ex. 68; Kinney 5/10/22 at 274.) But across both commercial and Part D purchases, Caremark paid Rite Aid an average price of AWP-78.768%—in between the prior two numbers. According to Relator, the negotiated average price between Caremark and Rite Aid for 2013 was AWP-78.60%—very close to the average price Caremark actually paid. (Smith Amended Opening Report, Table 3.) Because the average of Caremark's individual sale payments to Rite Aid (AWP-78.768%) was just slightly below what Caremark had promised (AWP-78.60%), Caremark would have to make only a small reconciliation payment to Rite Aid. (See Caremark's Ex. 49, Caremark's Answers to Interrogatories, at 12.) By contrast, if only Part D purchases were counted, Caremark

²² Neither set of purchases was a subset of the other because Part D purchases included purchases from multiple pharmacies, and Caremark did not have guaranteed average pricing terms with all pharmacies.

²³ The "-" referred to in these figures denotes subtraction. Thus, "AWP-80.443%" means the average wholesale price (AWP) minus 80.443%, or 19.557% of the AWP.

would have paid more than the promised average and would not have had to make a reconciliation payment at all. And, if only commercial purchases were counted, Caremark would have paid much less than the promised average and would have had to make a large reconciliation payment.

Caremark does not disagree with these numbers, but disagrees with Relator about how to interpret them. Caremark admits that, for Walgreens in 2013, the average of its Part D individual sale prices was higher than the negotiated average and the average of its commercial individual sale prices was lower than the negotiated average. (See Caremark's Response to Relator's Facts ¶ 162 at 2.b.) However, Caremark objects to considering the hypothetical scenario of what the reconciliation payment would have been for only Part D purchases or only commercial purchases because this "artificially appl[ies] Caremark's pharmacy GER guarantees separately to different groupings of claims that were bucketed together for purposes of the GER guarantees." (Caremark's Response to Relator's Facts ¶ 162 at 2.b (quoting Zavalishin Rebuttal Report ¶ 4.5).) In other words, Caremark asserts that because its promised average price with Walgreens applied across both Part D and commercial purchases, it is inappropriate to consider what Caremark's reconciliation payment might have been had only Part D or commercial purchases been included in the average. Caremark also insists that it did not "intentionally set higher prices for Part D drugs in exchange for setting lower prices for commercial drugs." (Caremark's Response to Relator's Facts ¶ 162 at 3.a (emphasis in original).) That is, while Caremark acknowledges the existence of a spread between Part D and commercial prices, Caremark denies that it intentionally created the spread or sought to have Part D and commercial prices balance each other. However, Caremark does not dispute the mathematical fact that including Part D purchases in the average resulted in a lower reconciliation payment than would have applied had the average included only commercial purchases.

F. Drug Prices Reported for Caremark's Clients

This section describes the drug prices that were actually reported on behalf of Caremark's clients Aetna and SilverScript. The respective roles of Caremark, Aetna, and SilverScript in producing those reports are discussed later in this Opinion.

1. Prices Reflected in PDE Records and DIR Reports

As described above, Part D sponsors were required to report drug spending through two types of reports: PDE records, which corresponded to individual drug purchases, and DIR reports, which summarized discounts and similar transactions that served to reduce the cost of drugs throughout the year. In PDE records, Caremark's clients reported Caremark's individual sale prices and not Caremark's guaranteed average prices. Similarly, Aetna's and SilverScript's DIR reports did not account for Caremark's guaranteed average prices with pharmacies. (Caremark's Facts ¶¶ 218, 289; Caremark's Ex. 49, Caremark's Answers to Interrogatories, at 9; Relator's Facts ¶ 142.) Thus, Caremark's clients reported Caremark's individual sale prices—and not Caremark's guaranteed average prices—as the cost of purchasing drugs for Part D members.

2. <u>Difference Between Reported Prices and Caremark's Guaranteed Average Prices</u>

As noticed previously, Relator's fraud claim is, in essence, that Caremark should have reported guaranteed average prices to CMS as the actual cost of drugs, as opposed to individual sale prices. In particular, Relator alleges that the individual sale prices Caremark reported were, for the years and pharmacies at issue, higher on average than the negotiated average prices, causing CMS to overpay in subsidies. Which prices should have been reported is a legal question that is discussed later in this Opinion. This section describes how the reported individual sale prices differed from Caremark's guaranteed average prices.

The parties agree that Caremark's individual sale prices differed from the average prices Caremark had negotiated with pharmacies—both individually and in the aggregate. That is, individual reported prices differed from the negotiated average prices, and the average of reported prices also differed from the negotiated average. (Caremark's Facts ¶ 288.)

Relator, through her experts, has offered numbers that she claims were the negotiated average prices for the pharmacies and years that support her claims. In Relator's view, these are the numbers Caremark should have reported. Caremark does not cite evidence disputing these numbers as to Walgreens and Rite Aid. (See Caremark's Response to Relator's Facts ¶ 139.) As noted, Caremark disputes the sufficiency of Relator's evidence as to the average pricing targets with CVS, but does not propose alternative numbers.

The numbers Caremark actually reported are more complicated because each individual sale had a different price, which could be more or less than the negotiated average. Relator proposes to understand these prices by looking at their averages. Using that approach, Relator's expert Dr. Smith offers numbers to compare the prices Caremark reported to the negotiated average prices. (Smith Amended Opening Report, Table 3.) Relator notes that, by this measurement, Caremark reported higher prices, on average, than the negotiated average for the pharmacy-year combinations that underlie her claims.²⁴ Of course, because these are averages, Dr. Smith's numbers do not mean that Caremark reported <u>all</u> Part D purchases at higher than the promised average—some could be higher and some could be lower. (See Caremark's Response to Relator's Facts ¶ 151.)

²⁴ Relator provides an alternative calculation using Caremark's pricing commitments to plan sponsors (Aetna and SilverScript) as a proxy for Caremark's reported prices. For purposes of this Opinion, it suffices to look at the average of Caremark's reported prices.

Caremark does not dispute that Dr. Smith's numbers accurately calculate the averages in question, although Caremark disagrees with Relator's characterization of these averages. (See Caremark's Response to Relator's Facts ¶¶ 140, 151 ("It is true that, at some pharmacies in some years, Caremark's aggregate payments to a pharmacy for Part D drugs—for all Part D plans for which Caremark served as the PBM—had a lesser average discount off AWP than the average discount off AWP provided in the pharmacy GER guarantee's price floor for all plans in aggregate (commercial and Part D)."), ¶¶ 164-69.) And, as noted previously, Caremark disputes the sufficiency of Relator's evidence as to the targeted average prices for CVS.

The parties also dispute whether comparing averages to averages is really an apples-to-apples comparison. In particular, Caremark notes that certain Part D subsidies such as the reinsurance subsidy were calculated on a member-by-member basis, such that an increase in average spending would not necessarily translate to an increase in subsidy. For example, an increase in spending that only affected members below the catastrophic threshold might not increase the reinsurance subsidy. See 42 C.F.R. § 423.329(c)(1) (effective March 22, 2005). Thus, Caremark asserts that looking at average reported prices is misleading. However, for present purposes, the average reported prices serve to illustrate, at a general level, Relator's allegation that Caremark reported spending more money than it actually spent.

G. Effect on Subsidies

Relator contends that price reports from Caremark's clients that contained individual sale prices rather than negotiated average prices caused the federal government to pay more in Part D

subsidies than it would have otherwise.²⁵ To support this conclusion, Relator relies on calculations performed by her expert, Dr. Loren Smith. (Relator's Ex. 43.)

As far as the parties' briefing reveals, there is no dispute as to the pricing figures Caremark's clients actually reported or the amounts of subsidies CMS actually paid.²⁶ Dr. Smith offers a calculation for what Caremark's clients would have reported, and CMS would have paid, had Caremark's clients used Caremark's average pricing commitments to pharmacies as the cost of drugs. It is that counterfactual calculation that Caremark disputes.

Dr. Smith calculates two different versions of how Caremark's clients could have reported negotiated average prices as the cost of drugs, but for purposes of this Opinion, it is only necessary to discuss what Dr. Smith calls his "DIR-based method." In that method, Dr. Smith assumed that Caremark's clients would have continued to include individual sale prices in PDE records but would have reported Caremark's negotiated average prices as price concessions. For example, if an Aetna Part D plan paid \$12 on an individual sale for drug X, but the cost of drug X would have been \$10 if measured using the negotiated average, Caremark would have reported \$2 as a price concession, effectively telling CMS that the \$12 payment should be reduced to \$10. Based on these calculations, Dr. Smith concluded that Caremark's reports caused CMS to overpay in subsidies. Across all years and pharmacies at issue, Dr. Smith calculated that the total effect would have been about \$274 million. (Smith Amended Opening Report ¶ 76-79.)

²⁵ Relator also contends that Caremark caused its clients to submit false bids (i.e., requests to sponsor a Part D plan) to CMS, but has not claimed damages stemming from those bids. (See Caremark's Facts \P 490.) Accordingly, this Opinion does not discuss any possible impact of false bids on the subsidies paid to Caremark's clients.

²⁶ Dr. Smith offers alternative calculations that substitute different numbers for what Caremark's clients actually reported (using average pricing terms as a proxy), but this Opinion does not discuss those calculations.

An added wrinkle, and the focus of Caremark's objection, comes from the fact that Part D sponsors were required to report price concessions on a plan-by-plan basis, because that is how subsidies were calculated. (See supra §§ III.B.2(b), III.B.3.) For reasons not explained in Dr. Smith's report, he did not add up price concessions for each individual purchase under each plan, but instead calculated a total price concession, which was then divided among Aetna and Silver-Script's various health plans, attributing a greater portion to plans that spent more on drugs. (See Smith Amended Opening Report, Appendix B, ¶ 123; see also Barlag Amended Rebuttal Report ¶ 74 ("Dr. Smith develops a Plan-specific allocation statistic equal to the percentage each individual Plan comprises of the Plan Sponsor's total ingredient cost amount in that Year.").)

Caremark does not contend that Dr. Smith performed his calculations incorrectly. (See Caremark's Response to Relator's Facts ¶ 206.) But Caremark's expert Brett Barlag does take issue with how Dr. Smith chose to allocate price concessions among Part D plans, in that Dr. Smith attributed some price concessions to plans that did not actually overreport individual prices. For example, a SilverScript Part D plan that Barlag calls "Plan Number 64" reported a lower average individual sale price (AWP-78.67%) in 2012 than the value Dr. Smith used for Caremark's average price target with CVS in 2012 (AWP-78.43%). The reason Dr. Smith still attributed a price concession to Plan 64 in 2012 is that, collectively, SilverScript's plans reported an average price of AWP-76.45% for CVS, and Dr. Smith spread that discount over all SilverScript plans, including Plan 64. (Barlag Amended Rebuttal Report ¶ 74-79.) Barlag does not argue that Dr. Smith allocated damages to Plan 64 due to a miscalculation or that doing so would have been impermissible under CMS's reporting rules, which allowed for allocation. (See Caremark's Ex. 57, 2011 DIR Reporting Requirements, § III.A.) Rather, Barlag's complaint is that allocating damages to Plan 64 would, in essence, call SilverScript's DIR entries for Plan 64 "false" when, in Barlag's view,

nothing SilverScript reported about <u>Plan 64 specifically</u> was false. However, Barlag does not contend that this alleged error meaningfully altered Dr. Smith's subsidy calculations. Furthermore, nothing in Barlag's report contradicts Dr. Smith's central thesis that Caremark's reports increased, overall, the subsidies paid to Aetna and SilverScript.

Other than referring to its motion to exclude Dr. Smith's testimony, which in turn refers to Barlag's criticism summarized above, Caremark does not dispute Dr. Smith's calculation showing how Aetna and SilverScript's reports affected Part D subsidies. (See Caremark's Response to Relator's Facts ¶ 206.) Caremark does take issue with Relator's legal characterization of Dr. Smith's conclusion—for example, Caremark disputes that negotiated average prices should have been accounted for in price reports. However, as a purely factual matter, Caremark offers no rebuttal to Dr. Smith's calculation showing that reporting average prices in the manner proposed by Dr. Smith would have led to a decrease in subsidies paid to Aetna and SilverScript.

H. Aetna and SilverScript's Roles Regarding Reporting Prices

Relator's fraud claims involve accusations that Caremark caused other entities (Aetna and SilverScript) to submit false price reports to the government rather than that Caremark submitted those false price reports itself. The parties dispute the allocation of responsibility among Caremark, Aetna, and SilverScript for ensuring the accuracy of these price reports.

By statute, only Part D sponsors (i.e., Aetna and SilverScript, but not Caremark) were required to submit pricing information as a condition of receiving subsidy payments. 42 U.S.C. § 1395w-115(d)(2)(A) (effective March 23, 2010). CMS regulations required contracts between Part D sponsors and their PBMs to include terms obligating PBMs to "comply with all applicable Federal laws, regulations, and CMS instructions." 42 C.F.R. § 423.505(i)(3)(v), (i)(4)(iv) (effective June 1, 2012). If a Part D sponsor submitted "claims data" to CMS that was "generated by" a

PBM, CMS regulations required the PBM to also certify to the accuracy of the data and to acknowledge that the data would be used for federal reimbursement. § 423.505(k)(3).

Consistent with its regulatory obligations, Caremark provided Aetna and SilverScript with attestations that: (1) the prices it reported were the "negotiated prices" for those drugs as defined in CMS's regulations; (2) it had reported all applicable price concessions; and (3) it understood that the information it supplied would be used for purposes of obtaining federal reimbursement. (Relator's Exs. 104, 111.) Caremark also submitted attestations to CMS directly regarding the accuracy of SilverScript's price reports. (Relator's Facts ¶¶ 192, 196.)

In practice, Aetna submitted its own price reports (PDE records and DIR reports) to CMS. (Caremark's Facts ¶ 284.) Aetna's Rule 30(b)(6) witness and former director of Medicare finance Clifford Passuello testified that Caremark provided "instructions" to Aetna on how to "calculate the dollar amount to be paid to the pharmacy," which would be "reported in the PDE data to CMS." (Passuello 10/18/22 at 109:24-110:8.)²⁷ Caremark concedes that it provided "pricing provisions" that Aetna used to adjudicate claims for payment. (Caremark's Response to Relator's Facts ¶ 178.) Aetna "implemented" those instructions "in an automated fashion" on its claims adjudication system to "calculate the exact dollar amount that [was] reported to CMS in the PDE data." (Passuello 10/18/22 at 110:10-17, 111:2-7.) Passuello further testified that Aetna "relied on Caremark to provide the PDE and DIR amounts that were then ... reported to CMS[.]" (Id. at 117:25-118:9.) While Caremark does not cite contrary evidence, it responds that it "cannot speak to Aetna's state of mind" regarding whether Aetna "relied" on Caremark's information to submit PDE records. (Caremark's Response to Relator's Facts ¶ 180.)

²⁷ Relator does not argue that this third-party testimony is binding on Caremark. Caremark does not object to its admissibility.

Although Aetna submitted its own DIR reports to CMS, "Caremark provided Aetna with a prepopulated DIR template, which included values for" certain categories of price concessions. (Relator's Facts ¶ 184.) Aetna, in turn, "did not change any of the values Caremark provided in the prepopulated DIR template." (Relator's Facts ¶ 186.) Aetna's former Vice President and Head of Medicare Part D, Terri Swanson, testified that Aetna "rel[ied] on information from [Caremark] to perform [Aetna's] DIR reporting." (Swanson 4/27/22 at 144:4-5; see also Passuello 10/18/22 at 51:13-24.) Caremark does not dispute that Aetna drafted its DIR reports based, in part, on "information from Caremark." (Caremark's Response to Relator's Facts ¶ 183.)

Regarding SilverScript, Caremark itself submitted PDE records to CMS on behalf of SilverScript. Caremark would send SilverScript draft DIR reports in a "CMS-ready format," which SilverScript would review and submit. (Caremark's Facts ¶¶ 285-86, 491; Meek 10/13/22 at 27-29; Caremark's Ex. 20 at CVS-BEHNKE-1090140.)

Caremark's contracts with Aetna and SilverScript gave the clients "ultimate responsibility" for fulfilling their obligations to CMS, but required Caremark to "certif[y]" the accuracy of information it provided. The contracts also gave Aetna and SilverScript certain rights to audit Caremark. (See Caremark's Facts ¶ 485; Caremark's Ex. 11 at CVS-BEHNKE-0000620; Caremark's Ex. 20 at CVS-BEHNKE-1090175.)

The parties disagree whether Aetna and SilverScript had the necessary information to exercise independent judgment over how to report drug prices. Aetna's Rule 30(b)(6) witness Passuello testified that, other than what Caremark included in DIR spreadsheets sent to Aetna, Aetna had no way of knowing "what price concessions Caremark received from pharmacies." (Passuello 10/18/22 at 75:25-76:11.) Aetna's Vice President, Head of Government Actuarial and Underwriting, Jean Walker, testified that she was not aware, for example, that in 2013 Caremark paid Rite

Aid above the guaranteed average on Part D purchases and below the guaranteed average on commercial purchases. (Walker 3/22/22 at 211:5-11; see also Swanson 4/27/22 at 163:2-9 (similar).)

Caremark does not dispute that its contracts with Walgreens and Rite and were "confidential" and, accordingly, Aetna and SilverScript did not have access to those pricing terms. (Caremark's Response to Relator's Facts ¶¶ 182, 195.) However, Caremark insists that its clients nevertheless "had visibility into Caremark's pricing arrangements with pharmacies." First, Caremark relies on a report by its expert that it was "industry standard" for Part D sponsors to have access to this type of information. (See Caremark's Response to Relator's Facts ¶ 182.) Second, Caremark emphasizes the history of its interactions with Aetna, in which Aetna's outside counsel was informed generally that Caremark sometimes paid higher prices on Part D purchases than on commercial purchases. (See infra § III.J.) Third, Caremark points to the contractual provisions, discussed above, that allowed Aetna and SilverScript to conduct audits.

I. Caremark's Alleged Motive Behind Its Pricing

As described above, for the pharmacies and years at issue, Caremark generally priced Part D purchases higher on average than commercial purchases while meeting its average pricing guarantees with pharmacies. This section describes Relator's evidence as to why Caremark set individual sale prices the way it did, which Relator contends is relevant to scienter.

Relator does not allege that Caremark priced Part D purchases higher so that it could obtain a higher subsidy from CMS. Subsidies were paid to Part D sponsors (Aetna and SilverScript), and the parties' briefing does not discuss whether Caremark received any share of those subsidies. Instead, Relator's theory is that Caremark sought to leverage certain pricing terms in its contracts with Part D sponsors to enable it to earn higher margin. While Relator does not contend that Caremark devised this scheme for the purpose of defrauding CMS or that leveraging its contracts to

extract higher margin was illegal by itself, Relator offers this evidence to show that Caremark understood it was reporting prices in a way that conflicted with the spirit of CMS's regulations.

Caremark's contract with Aetna provided for "pass-through" pricing, meaning Aetna would pay Caremark the same price Caremark paid the pharmacy, plus an administrative fee. Caremark also promised Aetna various guaranteed average prices, i.e., that Aetna would pay no more—but could pay less—than a negotiated average price across certain categories of drugs and plans. (See Caremark's Facts ¶¶ 101, 105, 170-73, 210, 218-19.) But the average price that Aetna was guaranteed to pay Caremark was, for some years and pharmacies, higher than the average price Caremark was guaranteed to pay the pharmacy. (See Relator's Facts ¶ 151 and Caremark's response thereto.)

Relator was an actuary in Aetna's Medicare department during the relevant time period, and, in that capacity, she claims to have noticed that Caremark was charging Aetna different prices than Caremark charged its other clients for the same drugs. Relator complained to Caremark that its prices were too high, and Aetna's former Vice President and Head of Medicare Part D, Terri Swanson, similarly told Caremark that Aetna "cannot be placed in a position of trying to explain to a member or to CMS that generic prices are going up, when all other data in the industry points the other direction." (Relator's Ex. 221 at AetnaBehnke-0032401; Caremark's Facts ¶¶ 269-71.)

According to Relator, Caremark initially responded that these prices were based on "marketplace conditions," but, by late 2012/early 2013, acknowledged that Aetna's competitors paid less, and Aetna's higher rates were set to maximize what Caremark was allowed to charge under their contract. (See Relator's Ex. 245; Behnke 246:19-247:6, 281:17-282:13; see also Caremark's Additional Facts ¶¶ 216-18.) Aetna requested that Caremark negotiate better prices with pharmacies, but, according to Relator's testimony, Caremark's Senior Vice President of Underwriting and

Actuarial, Allison Brown, responded that Caremark "already ha[d] better deals at the pharmacies" that were not being "pass[ed] ... along to" Aetna. Brown elaborated that the situation was "like a see-saw where ... if [Aetna] pa[id] less, then [Caremark] [would] have to pay more somewhere else." (Behnke 6/30/22 at 282:14-23; see also Caremark's Additional Facts ¶ 219.)

Brown's "see-saw" comment is highly significant to Relator's case for scienter, but the reason is subtle and requires explanation. As noted previously, Caremark had a "pass-through" contract with Aetna for Part D plans, such that Caremark was not supposed to earn money from drug purchases themselves but only through administrative fees. Thus, in theory, Caremark should not have objected to lowering Part D prices, because Caremark would earn the same administrative fee whether prices were high or low. In Relator's view, Brown's "see-saw" referred to Caremark's guaranteed average pricing terms with pharmacies: if Part D prices were pushed down, commercial prices would have to go up to keep the average constant, like a see-saw. But since Caremark was allowed to earn "spread" on commercial purchases, if commercial prices were pushed up, Caremark would earn less spread. (See Relator's Ex. 126, Caremark's Supplemental Response to Interrogatory No. 5.) Thus, according to Relator, Caremark was admitting that it was, in effect, profiting on Part D purchases because inflated Part D prices increased Caremark's spread on commercial purchases. And because CMS had stated that it did not want to subsidize PBM spread, Relator reasons that Caremark must have understood it was undermining at least the spirit of CMS's regulations.

A Caremark internal email corroborates Relator's understanding of the "see-saw" comment. In that email, Caremark's James Margiotta stated to Allison Brown and others: "In response to why we can't just give [Aetna] a better price and we shouldn't care, we should state that we have agreements with pharmacies that don't allow us to just price it at whatever the[] client wants

and it not cost CVS Caremark." (Relator's Ex. 268 at CVS-BEHNKE-0947604.) As with the "see-saw" comment, Relator reads Margiotta's statement that price concessions would "cost" Caremark to mean that Caremark was, in effect, earning spread on Part D purchases.

At some point in 2013, Caremark allegedly responded to Aetna's concerns by offering to reduce drug prices. A Caremark internal document reflects that these price concessions would hurt Caremark's profits. (Relator's Ex. 231 at AetnaBehnke-0193718; Margiotta 6/7/22 at 162:10-163:8.) Relator also claims that Caremark offered to negotiate better prices with pharmacies and to give Aetna 75% of the benefit—an offer Relator contends was inconsistent with "pass-through" pricing because Aetna should have received 100% of the benefit of any price concessions. (Relator's Ex. 271 at CVS-BEHNKE-1027333; Relator's Ex. 295 at CVS-BEHNKE-0165288; Relator's Ex. 298.) According to an email from Relator to others at Aetna, Caremark offered a "riskshare arrangement," prompting Aetna to inquire "how this complies with pass-through and what the associated reporting to CMS would look like," with Caremark responding to these questions by rescinding the proposal. (Relator's Ex. 231 at AetnaBehnke-0193720.) Relator views Caremark's offers of price concessions as suspect because Caremark should have been charging Aetna the same price it had negotiated with the pharmacy. Thus, in Relator's view, Caremark should have been unable to offer price concessions unless and until it negotiated better prices with pharmacies, and the fact that Caremark believed it could offer price concessions unilaterally showed that Caremark understood it was asking CMS to subsidize its own profits in addition to the cost of drugs.

Other Caremark internal documents could be read to suggest that Caremark understood it earned "value" from pass-through purchases. A Caremark internal slide presentation stated: "Changing a Pass through client[']s GER will have an impact on the amount of 'Value' we get

from Retail pharmacies in total." (Relator's Ex. 83, CVS-BEHNKE-0180214, at 180220.) According to Caremark's answers to interrogatories, this statement had a similar meaning to the "seesaw" comment described above: offering better prices to Part D clients could force Caremark to increase payments to pharmacies on commercial purchases to keep the average on target, causing Caremark to earn less margin ("spread") on commercial purchases. (Relator's Ex. 126, Caremark's Supplemental Response to Interrogatory No. 5.) In a similar vein, a factfinder could find that an internal Caremark slide presentation dated December 11, 2013 acknowledged that Caremark in effect earned "margin" on pass-through purchases for Part D clients. The document described an effort to make accounting for drug prices more accurate by defining a metric called "restated margin" that "combine[d] a specific client's proposed negotiated pricing arrangement rate with the pool of current client negotiated pricing arrangements against current COGS (pharmacy network rates)." (Relator's Ex. 265 at slide 10.) Relator views these documents as evidence of scienter because they show that Caremark was aware that its Part D prices affected its margin on commercial purchases—margin that CMS did not want to subsidize.

Relator offers other internal Caremark documents to show that Caremark's choice to earn "value" from pass-through purchases was a deliberate strategy rather than an accident. An internal Caremark slide presentation titled "Update on Network Strategy for Rite Aid," dated March 26, 2012, appears to show Caremark planning to pay Rite Aid more for Part D purchases than for commercial purchases in 2013 through 2015. (Relator's Ex. 313 at slide 11.) A similar slide presentation from September 7, 2012 again includes separate average prices for Part D and commercial payments to Rite Aid while noting that Caremark's "strategy" was to negotiate a single, overall average with Rite Aid. (Relator's Ex. 312 at slides 6-7.) Consistent with that alleged strategy, Caremark spreadsheets that Relator calls "reconciliation" workbooks show that, for certain

pharmacies and years, Caremark paid higher prices on Part D purchases than on commercial purchases, while paying an average price across all purchases that closely matched what Caremark had promised the pharmacy. (See supra § III.E.) In particular, Relator argues that because Caremark's documents reported these numbers separately for Part D and commercial purchases, Caremark must have been aware that higher-than-average Part D payments served to offset lower-than-average commercial payments, meaning Caremark understood it did not incur the full individual sale price on Part D purchases.

Relator also points to a Caremark document titled "Medicare Part D Pricing Guidelines" and purportedly authored by Caremark's "Legal" department, dated May 6, 2014, which set out six "guidelines" apparently aimed at preventing Caremark's negotiating team from offering pharmacies higher Part D prices in exchange for lower commercial prices. (Relator's Ex. 270.) To that end, the document prohibited employees from "seek[ing] to increase the plan's pass-through drug prices ... in whole or in part for the purpose of decreasing drug payments to pharmacies for commercial business," and exhorted them to remind pharmacies that participation in Part D networks was not conditioned on participation in commercial networks and vice versa. Relator places special emphasis on "Guideline 6," which stated: "Do not create documents that link how increased payments to pharmacies for Medicare Part D drugs may relate to reduced payments to pharmacies for commercial drugs." (Id. at CVS-BEHNKE-1024862.) Relator views this last statement as an admission that paying higher Part D prices in exchange for lower commercial prices would be inconsistent with Caremark's price reporting. Caremark responds that, in context, the document was only discussing possible issues under a different federal statute (the Anti-Kickback Statute) and was not related to Part D price reporting.

Finally, an internal Caremark slide presentation titled "Quarterly Pricing and Proposal Strategy Meeting," dated June 5, 2014, contained a section on "Client Ability to Audit Retail Network Contracts." (Relator's Ex. 260.) The presentation appears to suggest that Caremark's pass-through clients (e.g., Aetna) might view Caremark's average pricing terms with pharmacies as a "problem" because the average price could be lower than the price paid by the client. The presentation suggests "manag[ing]" this problem by executing a separate, client-specific contract with the pharmacy containing an average pricing term matching the client's prices, to "make[] the optics look better." (Id. at 27.) Relator reasons that Caremark must have understood that its pricing scheme could be viewed as problematic by its clients.

J. Aetna's Investigation into Caremark's Pricing

Both parties rely heavily on Caremark's interactions with Aetna to support their respective summary judgment positions on scienter, and Caremark also contends that these facts bear on falsity, materiality, and causation. In particular, Caremark asserts that Aetna became aware of, and then approved, Caremark's pricing decisions, breaking the causal link between Caremark and Aetna's price reports, and demonstrating that Caremark's interpretation of CMS's reporting requirements was reasonable.

1. Aetna's Compliance Concerns and Outside Counsel Investigation²⁸

Relator and others within Aetna had concerns about Caremark's conduct, including Allison Brown's "see-saw" comment, which they shared with Aetna's in-house counsel in early 2013. In a series of exchanges, Relator and other Aetna employees posed questions to Caremark, to which Caremark responded. However, Caremark's responses to these initial inquiries are not in the summary judgment record. (Caremark's Facts ¶¶ 295-303; Relator's Additional Facts ¶ 13.)

Aetna then retained outside counsel, Crowell & Moring LLP, in connection with Relator's concerns (and other issues related to Caremark). (Caremark's Facts ¶ 304.) The parties dispute whether Crowell & Moring's involvement could be called an "investigation" of those concerns—Relator asserts it was more of a formality (or "whitewash") to exculpate Aetna from possible future accusations of wrongdoing. (See Caremark's Facts ¶ 306 and Relator's response thereto.) Crowell & Moring posed additional questions to Caremark and received responses.

In a document marked "DRAFT 6/11/2013," Crowell & Moring set out facts represented to it by Caremark, which Crowell & Moring stated they had been unable to independently verify. Included were the basic facts of this case: that Caremark had guaranteed average pricing terms with some pharmacies that encompassed both Part D and commercial purchases, yet Caremark sometimes paid higher prices on the Part D side than the commercial side. The draft also described representations by Caremark that could be characterized as an attempt to explain the prior two facts in exculpatory terms: that the variance between Part D and commercial prices was "due to market conditions," and that Caremark did not negotiate lower commercial prices in exchange for higher Part D prices. Finally, the draft contained legal representations by Caremark that the prices

²⁸ Relator disputes the admissibility of some of the documents discussed in this section. Because these documents do not change the disposition of the parties' summary judgment motions, I do not address their admissibility.

it reported were the "negotiated prices" under CMS's regulations and that Caremark had accurately reported all price concessions and other DIR. (Relator's Ex. 301.)

Crowell & Moring's 2013 draft concluded that it had not "identified credible evidence that [Caremark]'s activities ha[d] resulted in overpayments to Aetna under the Medicare Part D program[] [or] that [Caremark] ha[d] violated the contract or applicable Medicare Part D requirements" The draft contained no legal analysis supporting that conclusion, and noted that it was contingent on factual and legal representations by Caremark that Crowell & Moring could not verify. Additionally, Crowell & Moring's 2013 draft recommended that Aetna conduct "additional follow-up" to verify that Caremark's reported prices were accurate. (Id. at AetnaBehnke-0193100.)

A document that appears to be Caremark's response to follow-up questions from Crowell & Moring, dated March 12, 2015, made a series of additional factual and legal representations about Caremark's Part D prices. (Relator's Ex. 309.) The March 2015 document began with a recitation of Aetna's concerns, noting, in particular, the question of whether prices for "non-Aetna Part D prescriptions" that were "lower than the guaranteed average price" were "a form of price concession" that should be reported, given that "those lower prices are to some degree arguably enabled ... by the higher Aetna Part D MAC prices"—essentially Relator's claim in this case. (Id. at AetnaBehnke-0193018.) In response to this concern, the March 2015 document made certain factual representations: Caremark "found no evidence that it and its pharmacies explicitly agree to accept lower commercial pricing and accept higher Medicare Part D pricing with the expectation that Medicare rates will offset, or otherwise make acceptable, lower commercial rates"; Caremark "did not find evidence that lower commercial rates are enabled by higher Medicare rates"; and "[e]ach line of business has separate and unique costs," because "[t]he regulatory requirements of

the Medicare Part D program add costs and burdens to plans and contracted pharmacies that are generally reflected in higher Part D negotiated prices." (Id. at AetnaBehnke-0193018 to 20.)

The March 2015 document also confronted the legal question of whether a guaranteed average pricing term covering both Part D and commercial purchases was reportable under CMS's rules. In Caremark's view, it was not: Caremark reasoned that CMS had permitted PBMs to negotiate simultaneously for Part D and commercial prices, had declined to require that Part D prices be as good as commercial prices, and had not listed aggregate pricing guarantees as an example of reportable price concessions despite listing many other examples in its guidance documents. Thus, Caremark inferred from CMS's silence on the issue (or its "lack of ... reference" to it) that CMS must not consider aggregate pricing terms to be reportable. (Id. at AetnaBehnke-0193021 to 22.)

Finally, Crowell & Moring authored a memorandum dated May 19, 2015, no longer labeled "draft," that "supplement[ed] and update[d]" its previous memorandum from 2013. (Relator's Ex. 302 at AetnaBehnke-0193102.) Although Crowell & Moring's 2015 memorandum presented Caremark's arguments for why its average pricing terms were not reportable, and noted that Caremark had "insisted" on this position, the memorandum did not contain Crowell & Moring's own analysis or conclusions on that specific question. The memorandum, did, however, note that Crowell & Moring had reviewed CMS guidance, and ended with the conclusion that, "unless and until CMS issues further guidance on DIR or otherwise addresses the type of guarantee arrangements [Caremark] has with retail pharmacy chains," Aetna could treat its concerns as "resolved"—adding the caveat that it had "not undertaken any independent factual investigation" and could not "predict with certainty how CMS or other officials or a fact-finder might view the scenario involved here." (Id. at AetnaBehnke-0193105 to 06.) As far as the summary judgment record reveals, neither Crowell & Moring nor Aetna's in-house counsel ever deviated from the conclusion that the issue

was "resolved." And, although Relator believes that Caremark's practices were inconsistent with Aetna's contract, as far as Relator is aware, Aetna did not accuse Caremark of breaching it. (Behnke 6/30/22 at 189:19-191:10.) In Caremark's view, these documents show that Aetna approved of Caremark's price reporting practices.

2. Switch to Direct Negotiation with Pharmacies

Aetna and Caremark signed a new contract, effective January 1, 2015, that allowed Aetna to negotiate directly with pharmacies for Part D pricing, a step Relator alleges was undertaken because Aetna no longer trusted Caremark to do the job honestly. (Caremark's Facts ¶ 330.) Although Aetna's direct contracts with pharmacies continued to use guaranteed average pricing terms, Aetna's then-Vice President, Head of Government Actuarial and Underwriting, Jean Walker, testified that Aetna did not adopt guarantees covering both commercial and Part D purchases because Aetna did not want to be "on the higher end of the range of [compliance] risk" the way Caremark was. (Walker 3/22/22 at 277:7-279:3; Caremark's Facts ¶ 332.) Caremark argues that Walker's statement must be understood in the context of Aetna's average pricing guarantees that were "two-way" (i.e., that sometimes required a reimbursement from the pharmacy), and the parties dispute whether this was a significant difference from how Caremark's guarantees worked. (See Relator's response to Caremark's Facts ¶ 334.)

K. CMS's Awareness of Caremark's Conduct

Caremark offers evidence regarding CMS's knowledge as bearing on three elements of Relator's fraud claims: falsity, materiality, and scienter. Caremark contends that CMS was aware of the nature of Caremark's pharmacy contracts and price reporting yet took no action. Caremark uses these facts to argue that: (1) its view of the meaning of CMS's reporting regulations must be correct, because CMS agreed with it; (2) any deviation from those regulations must not have been material; and (3) CMS's inaction left Caremark innocently unaware of any possible error.

1. CMS's Interaction with Caremark

CMS and Caremark employees conducted a call on March 8, 2016, which apparently included CMS employees with responsibilities for Part D price reporting. (Caremark's Facts ¶ 369; Caremark's Ex. 98 at CVS-BEHNKE-1859042.) Summarizing the call, Caremark employee David Azzolina identified CMS's "specific questions" as: "Describe how the Generic Effective Rate works. How does this flow, (i.e., POS adjustment, end result)?" (Relator's Ex. 26 at CVS-BEHNKE-1830849.) According to Azzolina, the "main focus" of the call was Caremark's average pricing terms, and "CMS questioned whether pharmacies were required to make true up payments to CVS Caremark under a [guaranteed average pricing term] should their reimbursement be more than the minimum guaranteed amount." (Caremark's Ex. 98 at CVS-BEHNKE-1859042.) Azzolina testified that he responded that pharmacies did not reimburse Caremark if Caremark's payments exceeded the guaranteed average. Azzolina elaborated that CMS did not ask any other "specific" questions about average pricing terms on that call and, once CMS received the response that pharmacies do not make reconciliation payments to Caremark, CMS "seemed like they had accomplished what they were wanting to accomplish ... and wanted to move on" (Azzolina 6/15/22 at 105:12-15, 107:20-108:3.)

On May 26, 2016, Azzolina sent a follow-up email to CMS employees. That email stated, in part, that Caremark had guaranteed average pricing terms with "a few pharmacies," and that these terms applied "across the pharmacy book of business," a phrase that Caremark alleges meant that the guarantees applied across Part D and commercial purchases. The email clarified that the guarantee set a "minimum" price, and "[p]harmacies do not make true up payments" in the event Caremark overpaid. Azzolina further stated that these guaranteed average terms were "not associated with additional arrangements that reduce the price, such as DIR arrangements with pharmacies where there may be an agreed upon incentive payment and/or discount based on pharmacy

performance." And Azzolina asserted that Caremark had "transparent" (i.e. pass-through) pricing with Part D sponsors, and these pass-through prices were "not altered by the guarantee to the pharmacy." (Relator's Ex. 26 at CVS-BEHNKE-1830849.)

Relator contends that Caremark's communications to CMS on the call and in the follow-up email were misleading. Relator takes issue with Azzolina's response that pharmacies did not reimburse Caremark for above-average prices, because, in Relator's view, the ability of Caremark to use above-average payments on Part D purchases to offset below-average payments on commercial purchases was essentially the same as a reimbursement from the pharmacy. (See Relator's Response to Caremark's Facts ¶ 373.) Relator also complains that the sentence "[t]he GER is also not associated with additional arrangements that reduce the price" was misleading because such offsetting, in Relator's view, did reduce the price in that it allowed Caremark to purchase Part D drugs more cheaply than the price reflected on an individual sale.

2. <u>Discussions Between CMS and Aetna</u>

Caremark also claims that CMS was informed of Caremark's price reporting practices through its interactions with Aetna, including with Relator herself. Although it is undisputed that Aetna informed CMS that it had concerns with Caremark's conduct, the parties dispute whether those were the same concerns that underlie Relator's fraud claims here, or whether they pertained to different issues.

In February 2015, CMS auditors met with Aetna actuaries. In an email, Aetna employee John Wells summarized the interactions among CMS, Relator, and himself, writing that Relator "discussed with the auditors her concerns with the DIR issue and CVS [Caremark] (as a PBM)." According to Wells, CMS responded that "they had heard this concern from other plans, view it as an industry issue versus a plan specific issue, and had asked us to share with them the response we receive from CVS as a follow-up with them on this matter." In another summary of the meeting,

Aetna employee Meegan Johnson wrote, in a statement attributed to Relator, that "We do rely on PBM but they provide an Attestation; we disclosed last week that there is an investigation currently in process with CVS [Caremark] on this." (Caremark's Ex. 100 at AetnaBehnke-0913068-69.)

In interpreting the above documents, Caremark does not point to evidence further elaborating on what the "DIR issue" was, in particular whether it was the same as Relator's concerns about Caremark's reporting of guaranteed average prices. Similarly, Caremark does not point to evidence on what the referenced "investigation" was or whether it related to the "DIR issue" or Relator's allegations in this case. In deposition testimony, Relator could not recall what the "DIR issue" was or whether it pertained to her allegations in this case, but speculated that it probably did not. (See Behnke 6/30/22 at 322:14-323:17.)

3. Other Evidence of CMS's Awareness of General Pricing Practices

Caremark offers other evidence to show that CMS was generally aware of concepts such as MAC pricing and guaranteed average pricing, from which Caremark argues CMS could have inferred that PBMs were engaging in practices such as those at issue in this case.

CMS documents show that CMS was generally aware that PBM's could set individual sale prices when purchasing drugs, and could set different prices depending on the pharmacy and plan. (See Caremark's Facts ¶¶ 342-45, 346-51.) Caremark's evidence regarding CMS's knowledge of guaranteed average pricing is less direct, and consists of documents that reference guaranteed average pricing in the context of discussions of other topics.

For example, a document purporting to be a letter from a member of the public to CMS states that "PBMs manipulate MAC prices to ensure that their contractually obligated effective discount ... is met" and "if they [PMBs] have overpromised a[n] [average price] to a plan sponsor they must ... adjust[] MAC prices to below acquisition cost on some agents," which Caremark reads to mean that PBMs sometimes adjusted MAC prices to meet guarantees to plan sponsors (as

opposed to pharmacies). (Caremark's Ex. 96 at CMS_0000353.) Caremark also points to an email from a member of the public to CMS that quotes provisions from a larger contract containing guaranteed average terms, although those terms are not the subject of the discussion. (Caremark's Ex. 90b at CMS_000381.) Another email, apparently internal to CMS, quotes a recommendation from the National Association of Chain Drug Stores (NACDS) that guaranteed average pricing could be beneficial in Medicaid (as opposed to Medicare) because it provides more predictable reimbursement to pharmacies. (Caremark's Ex. 92 at CMS_0000354.) Finally, an email from the National Community Pharmacy Association (NCPA) in 2015 states that an average pricing term can serve as a "guardrail" that "ensure[s] that pharmacies would receive adequate reimbursement for generics (and average reimbursement on generics) particularly when MAC pricing goes too low or is sharply discounted," although such guarantees are "usually negotiated on a plan by plan basis." (Caremark's Ex. 95 at CMS_0000271.)

4. CMS's Lack of Action Against Caremark

Caremark points to evidence that, despite CMS's alleged awareness of Caremark's pricing practices, no enforcement action was taken. Three Caremark employees (David Azzolina, Rebecca Justice, and Terri Swanson) signed declarations stating that to the best of their knowledge, CMS has never performed any audits, requested return of any funds, imposed any penalties, or took other remedial action with respect to Caremark's reporting of guaranteed average prices. (Caremark's Exs. 102, 103, 104.)

According to Caremark's expert Leslie Norwalk, if CMS employees learn of a possible compliance concern in their conversations with industry participants, they will "alert the appropriate and knowledgeable personnel within the agency," and CMS will make follow-up inquiries. (Norwalk Amended Opening Report ¶ 230.) Caremark therefore contends that CMS's silence indicates that CMS was not concerned about Caremark's price reporting practices.

The Government became aware of Relator's fraud claims through the instant <u>qui tam</u> suit, which it then investigated. (Behnke 6/30/22 128:18-129:1.) As far as the summary judgment record reveals, the Government never intervened in this lawsuit or brought any of its own claims against Caremark related to Caremark's reporting of guaranteed average prices.

IV. LEGAL STANDARD

Summary judgment is proper "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A dispute is "genuine" if there is evidence from which a reasonable factfinder could return a verdict for the non-moving party, and a dispute is "material" if it might affect the outcome of the case under governing law. Kaucher v. County of Bucks, 455 F.3d 418, 423 (3d Cir. 2006) (citing Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986)). The court must view the evidence in the light most favorable to the non-moving party. Galena v. Leone, 638 F.3d 186, 196 (3d Cir. 2011). However, "unsupported assertions, conclusory allegations or mere suspicions" are insufficient to overcome a motion for summary judgment. Schaar v. Lehigh Valley Health Servs., Inc., 732 F. Supp. 2d 490, 493 (E.D. Pa. 2010) (citing Williams v. Borough of W. Chester, Pa., 891 F.2d 458, 461 (3d Cir. 1989)).

The movant "always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." <u>Celotex Corp. v. Catrett</u>, 477 U.S. 317, 323 (1986). Where the non-moving party bears the burden of proof on a particular issue at trial, the moving party's initial <u>Celotex</u> burden can be met by showing that the non-moving party has "fail[ed] to make a showing sufficient to establish the existence of an element essential to that party's case." <u>Id.</u> at 322.

After the moving party has met its initial burden, summary judgment is appropriate if the non-moving party fails to rebut the moving party's claim by "citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations ..., admissions, interrogatory answers, or other materials" that show a genuine issue of material fact or by "showing that the materials cited do not establish the absence or presence of a genuine dispute." Fed. R. Civ. P. 56(c)(1)(A).

V. <u>DISCUSSION</u>

A. Falsity as to Walgreens and Rite Aid

The parties disagree as to whether Aetna and SilverScript's Part D price reports for the pharmacies and years at issue were false. This section discusses reports with respect to Walgreens and Rite Aid. (Price reports for CVS, which raise unique issues, are discussed in the next section.)

The underlying facts regarding Caremark's transactions with the pharmacies and the prices that were reported are not in dispute. Instead, the parties' dispute is a legal one over what prices were required to be reported under CMS's regulations. As best I can frame it, one of the significant disputes in this case comes down to the following issue: If a PBM contracted with a pharmacy to pay at least a certain average price across all drug purchases (both Part D and commercial), and the PBM in fact paid no more than that guaranteed average, and the PBM's Part D individual sale payments differed on average from that guaranteed average, which price was the Part D sponsor required to report?²⁹ Put more simply, would an accurate report be the individual sale price or the guaranteed average? To answer this question, a careful examination of the CMS regulations is required.

²⁹ As this sentence could not be shortened, despite best efforts, I offer apologies to Mark Twain, who may have said, "I didn't have time to write a short letter, so I wrote a long one instead."

1. "Actually Paid" Costs

To determine which prices were required to be reported, I begin with the regulatory term "actually paid." This is because the purpose of price reporting was to inform CMS how much each Part D plan paid for drugs so that CMS could calculate the appropriate subsidy, which depended only on amounts "actually paid." (See Relator's Facts ¶ 197 (citing 42 U.S.C. § 1395w-115(d)(2)(A) (describing authority to require price reports)); Caremark's Ex. 55, 2011 PDE Guide § 1.6.4 (describing how reports would be used to calculate subsidies).) It is therefore necessary to look to the regulatory term "actually paid" to determine which price—the individual sale price or the guaranteed average price—most accurately fit that term's definition.³⁰

The regulation defined "actually paid" costs as costs that were: (1) "actually incurred," (2) adjusted for price concessions and other "direct and indirect remuneration" (DIR), and (3) the "negotiated prices" between the PBM and the pharmacy. (Supra § III.B.1.) Of these three requirements, the most informative for present purposes is "actually incurred." To better understand this term as used in the CMS regulations, suppose an Aetna Part D member purchased drug X from Walgreens, and that Caremark's negotiated average price that drug was \$10 but Caremark paid \$15 to Walgreens for that individual sale. Even though Caremark initially put down \$15, the total amount of money that would actually leave Caremark's pocket by the end of the year would be \$10, not \$15. This result was driven by Caremark's obligation to reimburse based on end-of-year averages. Every extra dollar above \$10 that Caremark gave Walgreens for this purchase would be one dollar less that Caremark would have to pay Walgreens by the end of the year to make the average \$10. Conceptually, Caremark would get \$5 back. Various additions and subtractions might

³⁰ The Government filed a "statement of interest" in connection with the present motions for summary judgment but did not take a position on the meaning of CMS's regulations. (ECF No. 312.)

occur over the course of the year before Caremark ultimately paid \$10, but moving these sums back and forth would not change the fact that Caremark was ultimately obligated to pay \$10 for every purchase of drug X. By contrast, the fact that Caremark chose to put down \$15 on this particular sale would have no impact on its overall obligation to Walgreens. Therefore, Caremark would "actually incur" \$10—the guaranteed average price—rather than \$15 (the individual sale price).

A further analogy may make this point clearer. As commonly occurs, suppose a service provider offers to buy a client dinner. At the restaurant, each person's dinner costs \$50 (excluding gratuity and tax), and thus \$100 is the total paid by the provider. Later in the evening, the provider privately asks the sever to record the check as \$70 for the client's dinner and \$30 for the provider's dinner. The server, indifferent to this unusual accounting request because it does not alter the \$100 total, agrees. The provider, wishing to impress the client, then says, "your dinner cost \$70, my treat." This scenario does not however change the fact that the client's dinner actually cost the provider \$50, regardless of how it is recorded on the bill. The same reasoning applies here: regardless of how Caremark may have recorded the price of each individual purchase, this would not change the fact that each individual Part D purchase would increase what Caremark was out-of-pocket by the guaranteed average price—and only the guaranteed average price.

Caremark offers several reasons why negotiated average prices did not count as "actually paid," but none are persuasive. First, Caremark argues that negotiated average prices were not the prices of "particular drugs," referencing a phrase that appeared in the definition of a different regulatory term but not in the definition of "actually paid." Specifically, Caremark points to the definition of "gross covered prescription drug costs," which incorporated the term "actual cost," which in turn incorporated "negotiated prices," which, finally, were defined as "prices ... that[] ... [t]he

[PBM] and the network dispensing pharmacy ... have negotiated as the amount [the pharmacy] will receive, in total, for a <u>particular drug</u>." 42 C.F.R. § 423.100 (effective June 7, 2010) (emphasis added). Caremark argues that because a guaranteed average price covered multiple drugs, it was not the price of a "particular drug." I disagree with this reasoning.

The CMS regulation did not require that "actually paid" prices be the prices of "particular drugs": the definition of "actually paid" did not incorporate, directly or indirectly, the phrase "particular drug," and the regulation contemplated that "actually paid" costs could be a "subset" of other drug costs. See 42 C.F.R. § 423.308 (effective June 7, 2010). Even if the phrase "particular drug" did apply to the definition of "actually paid," however, there is no inconsistency between the negotiated average price being the price of multiple drugs and it also being the price of each "particular drug" in that set. Using another food analogy, if a store sells apples for \$2, that is the price of that "particular fruit," irrespective of whether the store also sells oranges for the same price.³¹

Caremark next argues that its obligation to the pharmacy was not solely to pay the correct average price by year's end but also to pay the correct individual sale price on each purchase as determined by the "lower of" formula in the contract. (See supra § III.D.) Caremark therefore asserts that the individual sale price was "actually incurred," because Caremark was not free to deviate from it. (Caremark makes this argument even though it concedes that one input to the "lower of" formula—the MAC price—was under its control.) However, even if Caremark is correct that

³¹ Caremark makes a similar argument based on CMS's statement in a rulemaking that "negotiated prices are based upon the actual drug price paid at the point-of-sale" 74 Fed. Reg. 1494, 1505 (Jan. 12, 2009). The full quote, however, reveals that CMS was only discussing whether cost-sharing payments should include PBM administrative fees, and was not making a distinction between individual sale prices and aggregate prices. But even if CMS were making such a distinction, it was interpreting "negotiated price," not "actually paid" costs, and "actually paid" costs could be a subset of other costs. 42 C.F.R. § 423.308 (effective June 7, 2010).

the individual sale price was obligatory, Caremark did not "incur" all of it: Caremark's overall indebtedness to the pharmacy would only increase by the guaranteed average price, and any amount by which the individual sale price exceeded the guaranteed average would be recouped by year's end.

Finally, Caremark insists that treating negotiated average prices as "actually incurred" conflicts with common sense, because that approach looks at a contractual term rather than the discrete movement of dollars between Caremark and the pharmacy. Caremark offers as an example that in 2011, it and Rite Aid had separate guaranteed average terms for Part D and commercial purchases. During that year, Caremark paid Rite Aid more for Part D drugs than required by the guaranteed average, and Relator concedes that those individual sale prices were "actually incurred," because Rite Aid had no obligation to return the excess to Caremark. (See Caremark's Response to Relator's Motion for Summary Judgment at 21.) If, however, Caremark and Rite Aid had had a guaranteed average price covering both Part D and commercial purchases for 2011, Relator's theory would be that the individual sale prices would no longer be "actually incurred," and instead the guaranteed average price would be "actually incurred." Caremark insists that this result is counterintuitive because the same movement of dollars might or might not count as "actually incurred" depending on whether there was also a guaranteed average price at play.

I disagree that this result is counterintuitive. If there is a guaranteed average price covering both Part D and commercial purchases, every above-average payment on a Part D purchase reduces the reconciliation payment that Caremark would otherwise have to make due to below-average payments on commercial purchases, and it is therefore sensible to account for this credit in determining how much of the individual sale price is "actually paid." In fact, Caremark's example of Rite Aid in 2011 proves this point. If Caremark and Rite Aid had had a guaranteed average price

covering both Part D and commercial purchases for that year, Caremark would have owed Rite Aid millions of dollars less in its end-of-year reconciliation payment. (Relator's Ex. 33, Barlag Amended Rebuttal Report, ¶ 50.) It is therefore not accurate to say that the same movement of dollars would have occurred with and without a guaranteed average price spanning Part D and commercial purchases. And there is nothing odd about saying that a contractual term that would have saved Caremark millions of dollars would also have reduced what Caremark "actually paid."

Finally, Caremark insists that its individual sale prices reflected market forces and that it did not intentionally negotiate higher Part D prices to offset lower commercial prices, offering expert testimony that Medicare Part D drugs could cost more than commercial drugs for legitimate reasons. Assuming these facts are true, though, they would not affect what Caremark "actually paid." Whether intentionally or not, Caremark incurred the same negotiated average price on each purchase, Part D and commercial, and that is the price Caremark "actually paid."

For these reasons, I conclude, as a matter of law, that when Caremark had a guaranteed average price with a pharmacy, and Caremark's individual sale prices in the aggregate fell below that guaranteed average, the amount Caremark "actually paid" was the guaranteed average price and not the individual sale prices. Accordingly, the correct calculation of the subsidies to which Aetna and SilverScript were entitled depended on Caremark's negotiated average prices, not individual sale prices. 42 C.F.R. § 423.308 (effective June 7, 2010).

2. Required Content of Drug Spending Reports

Having determined that the prices Caremark "actually paid" for the pharmacies and years at issue were its guaranteed average prices, I next address what prices Aetna and SilverScript were required to report to CMS. This analysis is complicated by the fact CMS regulations called for two separate types of price reports—PDE records for individual drug purchases, and DIR reports for other transactions that reduced the price of drugs. Relator argues that Caremark's clients should

have used these documents to report the negotiated average prices that Caremark "actually paid," while Caremark insists that only individual sale prices had to be reported. For the reasons set out below, I conclude that Aetna and SilverScript were required to submit PDE records and DIR reports that, collectively, reflected the prices Caremark "actually paid"—i.e., Caremark's guaranteed average prices.

Caremark does not contest the general notion that reported prices were supposed to align with "actually paid" prices. Instead, the essence of Caremark's argument is that it was impossible to fit negotiated average prices into the price-reporting framework that CMS had constructed—that is, PDE records and DIR reports. Caremark focuses narrowly on the language defining the contents of PDE records and DIR reports and argues that neither type of report was compatible with negotiated average prices.

I begin by emphasizing that the stated purpose of reporting prices to CMS was to obtain the information necessary to calculate subsidies—i.e., "actually paid" prices. CMS instituted price reporting pursuant to its statutory authority to collect "such information as may be required" to carry out its responsibilities, including calculating the reinsurance subsidy and risk-corridor payments. (Relator's Facts ¶ 197 (citing 42 U.S.C. § 1395w-115(d)(2)(A)).) CMS's document defining the content of PDE records described how PDE records and DIR reports would be used, collectively, to calculate subsidies. (See, e.g., Caremark's Ex. 55, 2011 PDE Guide § 1.6.4.) And CMS's document defining the content of DIR reports similarly stated that "Section 1860D-15(f)(1)(A) of the Social Security Act (SSA) requires Part D sponsors to fully disclose to CMS any information necessary for carrying out the payment provisions of Part D, including the calculation of reinsurance and risk sharing. Therefore, Part D sponsors are required to report drug costs

and DIR associated with the Medicare prescription drug benefit to CMS." (See Caremark's Ex. 57, 2011 DIR Reporting Requirements § I.B, p. 6.)

Consistent with that stated purpose, CMS defined the content of PDE records and DIR reports such that they would reflect what each Part D sponsor "actually paid" for covered drugs. CMS's document on PDE records specified that these records were to contain the "gross covered prescription drug cost" (or, sometimes, "gross covered drug cost") for a purchase, with a citation to the definition of that term in 42 C.F.R. § 423.308. That regulation, in turn, defined the "gross covered prescription drug cost" to be the amount that was "actually paid." CMS's PDE guidance further specified that "[a]ny DIR that [was] not reflected in the cost of the drug on the PDE record" had to be included in DIR reports. (See Caremark's Ex. 55, 2011 PDE Guide § 1.5.2.2; Caremark's Ex. 57, 2011 DIR Reporting Requirements.) And, as described above, DIR was defined in CMS's regulation as any price concessions or similar transactions that would serve to reduce what the Part D sponsor or its PBM "actually paid." (Supra § III.B.1(b).)

The parties agree that there were two ways Caremark's clients could have used the PDE and DIR reporting framework to report negotiated average prices: First, Caremark's clients could have reported negotiated average prices directly in PDE records. Second, Caremark's clients could have reported individual sale prices in PDE records but used DIR reports to account for Caremark's negotiated average prices. (See Caremark's Ex. 55, 2011 PDE Guide § 1.5.2.2 (requiring price adjustments "not reflected in the cost of the drug on the PDE record" to be included in DIR reports); Craft 2/17/23 at 26:18-20 (Relator's expert conceding either method of reporting would be "acceptable").) That is, there were two "buckets" that could hold negotiated average prices to comply with the regulatory purpose to report actually paid prices: the "PDE bucket" and the "DIR bucket." While Relator does not contend that either bucket was legally required over the other, she

does contend that negotiated average prices had to be reported in at least one of these buckets to accurately reflect negotiated average prices.

Caremark's principal argument is that neither bucket could contain negotiated average prices. In effect, Caremark's position is that there was a gap between PDE and DIR reporting requirements: some third way to move value between Caremark and the pharmacy that was neither the "price" of a drug required to be included in PDE records nor a "price concession" required to be included in a DIR report. Thus, under Caremark's theory, its clients were free to report individual sale prices in PDE records and not account for any savings attributable to the guaranteed average price in DIR reports.

To refute Caremark's argument, it is only necessary to find that either PDE records or DIR reports would have been an appropriate way to report guaranteed average prices—it is not necessary to find that both would have been appropriate. Because the analysis is simpler, I address Relator's argument that negotiated average prices could have been factored into DIR reports. That is, Relator contends that if the negotiated average price for a drug was \$10, and Caremark paid the pharmacy \$12 on an individual sale, the corresponding \$2 reduction in Caremark's year-end obligation to the pharmacy was a "price concession" that should have been included in a DIR report.

Relator argues that her interpretation is correct as a matter of ordinary language, in that a \$2 reduction in what Caremark owed the pharmacy would be a \$2 "price concession[] or similar benefit[]," which "would serve to decrease the costs incurred under the Part D plan." Moreover, failing to report the \$2 price concession would result in Caremark's client telling CMS it had incurred a cost of \$12 to purchase the drug when in fact Caremark was only out of pocket \$10. Caremark responds that only concessions in the prices of Part D drugs themselves were reportable. In Caremark's view, its end-of-the-year reconciliation payment was not the price of a Part D drug,

but, rather, a complicated contractual term depending on both Part D and commercial drugs. Thus, Caremark posits that reductions in an end-of-year reconciliation payment were not reportable, even if those reductions occurred based on Caremark's Part D spending.

Caremark's interpretation of CMS's regulation is not persuasive. The regulation did not contain the limitation that reportable price concessions only consisted of discounts on Part D drugs themselves, and the "starting point on any question concerning the application of a regulation is its particular written text." Lewis v. Atlas Van Lines, Inc., 542 F.3d 403, 409 (3d Cir. 2008). Caremark points instead to a paraphrase of this regulation in another CMS document that described reportable price concessions as "any and all rebates, subsidies, or other price concessions from any source ... that serve to decrease the costs incurred by the Part D sponsor (whether directly or indirectly) for the Part D drug." (Relator's Ex. 160 at 6 (emphasis added).) Even if the phrase "for the Part D drug," were part of the regulation, it would not mean that a price concession was only reportable when it was "on a Part D drug," because a reduction in what Caremark owed the pharmacy under a guaranteed average pricing term would nevertheless decrease the cost "for" the Part D drug: any amount by which the individual sale payment exceeded the negotiated average would be recouped at the end of the year in the form of a reduced reconciliation payment, which reduced the cost to Caremark of purchasing Part D drugs.

This interpretation is confirmed by the fact that CMS's list of examples of reportable price concessions included "reduced-price services," which could not have included Part D drugs because drugs are not services. Moreover, reporting price concessions in end-of-year DIR reports only made sense if those price concessions were not already reflected in the price of the drugs themselves. See Kisor v. Wilkie, 139 S. Ct. 2400, 2424 (2019) (structure and purpose should be considered in interpreting regulations). Finally, since the purpose of reporting price concessions

was to arrive at the prices Caremark had "actually incurred," it was essential that price concessions related to Caremark's guaranteed average pricing contracts be included in end-of-year DIR reports so that CMS could calculate a correct subsidy. See 42 C.F.R. § 423.308 (effective June 7, 2010).

Caremark's next argument, which is somewhat difficult to understand, is that the difference between individual sale prices and negotiated average prices was not a reportable price concession because it involved a comparison between two different "universe[s] of drugs." (See Caremark's Response to Relator's Motion for Summary Judgment at 15.) Caremark notes that individual sale prices depended on MAC prices, which Caremark had adjusted to meet commitments to its clients Aetna and SilverScript. By contrast, negotiated average prices with pharmacies applied to all drug purchases—Part D and commercial—from just that one pharmacy. Caremark argues that it is not sensible to compare prices between those two "universes." As best I can understand this argument, it appears to confuse the process by which drug prices were set with the prices themselves. If Caremark paid an individual sale price that was higher than the guaranteed average price, that excess payment would reduce Caremark's end-of-year reconciliation obligation to the pharmacy and thus constitute a reportable price concession. This would be true regardless of whether Caremark might have considered its commitments to other parties when setting the individual sale price. Put another way, the process by which individual sale prices were set would have no bearing on what Caremark was ultimately obligated to pay the pharmacy under its contract.

Finally, Caremark argues that it was not required to report price concessions based on guaranteed average prices because there was an "industry custom" against reporting such price concessions. Caremark asserts it was understood in the industry that "DIR does not extend to anything of 'value' that might be conceived of as benefiting a Plan Sponsor or PBM in some abstract manner. Rather, at a fundamental level, DIR concerns discrete, identifiable payments, discounts, or

adjustments to/from Plan Sponsors or PBMs related to covered Part D drugs." (Caremark's Response to Relator's Motion for Summary Judgment at 20 (quoting Norwalk Amended Opening Report ¶ 235).) Caremark has not provided a single example of another Part D sponsor or PBM that reported prices consistent with this alleged custom. Still, even assuming the alleged custom did exist, the text of CMS's regulation was clear that all price concessions that served to reduce the cost of Part D drugs had to be reported, and thus its interpretation would not be altered by contrary practice in the industry.

For these reasons, I conclude that, as a matter of law, Aetna and SilverScript's price reports were required to reflect the prices Caremark "actually paid" for Part D drugs, which was Caremark's negotiated average price with the pharmacy. To the extent Aetna and SilverScript's PDE records reflected only individual sale prices, Aetna and SilverScript were required to account for the difference in their DIR reports.

3. Falsity of Actual Reports

It is undisputed that price reports for Caremark's Part D sponsor clients did not reflect Caremark's negotiated average prices with Walgreens and Rite Aid. (Supra § III.F.) As a matter of law, those reports were therefore false, and partial summary judgment on this issue will be granted in favor of Relator.

B. Falsity as to CVS

The parties agree that: (1) Caremark and CVS did not have a contract setting an average price that Caremark was required to pay; but (2) Caremark and CVS did have a "target" for the average price in at least some years. The parties disagree as to whether this target was "negotiated" and whether Caremark was required to meet it. The parties also disagree as to whether Relator has sufficient evidence for the numerical values of this target, although Caremark does not propose

alternative numbers. Both parties seek summary judgment in their favor on these issues, except that Relator is not seeking summary judgment for the years 2011 and 2012.

1. 2013 through 2016

For 2013 through 2016, the parties agree that Caremark and CVS had a "target" average price, but disagree as to whether that target was what Caremark "actually paid" for drugs.

(a) Whether the Average Price Target Was What Caremark "Actually Paid"

For the reasons explained above, when Caremark had a contractual obligation to Walgreens and Rite Aid to pay at least a certain average price for drugs, and in fact paid no more than that average price, the negotiated average was what Caremark "actually paid." The reason is that Caremark's overall indebtedness to the pharmacy would increase by the negotiated average price for each purchase, regardless of what price Caremark put down at the time of sale. The present dispute is whether similar reasoning could apply to CVS, where there was not a formal written contract but rather some other type of arrangement on what the average price would be.

Relator's position is that Caremark and CVS "negotiated" for an average price and then reached an "agreement" or "deal" for what that price would be. Relator insists there was a "fire-wall" between Caremark and CVS, such that Caremark was "not able to dictate pricing" and instead was required to pay the "contracted rates." Relator also points to evidence that Caremark treated the average price as a "cap" to which Caremark was "committed," in a way that was not "different, in all practical purposes," from how Caremark treated its relationships with Walgreens and Rite Aid. (Supra § III.D.2(a).) Relator also points to evidence that Caremark's actual payments to CVS closely matched the targeted average. (Supra § III.E.)

By contrast, Caremark insists that it and CVS essentially acted as "one company," and did not negotiate any prices other than what was in their written contract. While Caremark acknowledges that there was an average price target, Caremark maintains that the goal of this target was to maximize the benefit to the "total enterprise," rather than as a compromise between opposing interests. Caremark does not offer evidence that its payments deviated from the targeted average, but disputes that this was due to any obligation on its part, and notes that it never made "reconciliation" payments to CVS if the individual sale prices fell short of the target. (Supra § III.D.2(a).)

CMS's regulations did not define "paid" or "incurred," but did define "cost" as "negotiated price" in the case of an in-network pharmacy, such as CVS. 42 C.F.R. § 423.100 (effective June 7, 2010). In addition, while neither party offers authority on the meaning of these terms beyond their regulatory definitions, both parties appear to view price as pseudo-contractual—that is, the amount of money Caremark was required to give up in order for the insured member to obtain drugs from the pharmacy.

The evidence in the summary judgment record is not conclusive on the question of whether the "targeted" average price between Caremark and CVS was what Caremark "actually paid." If a factfinder were to credit Relator's evidence, it could determine that Caremark and CVS "negotiated" the average price as that term was used in 42 C.F.R. § 423.100, and that both sides viewed the outcome of their negotiation as obligatory. On the other hand, a factfinder could also accept Caremark's version that the targeted average was more of an accounting formality and did not reflect any obligation on Caremark's part. Accordingly, summary judgment will be denied to both parties on the issue of whether Caremark's targeted average prices with CVS were what Caremark "actually paid" in 2013 through 2016.

(b) What the Average Price Targets Were

Although Caremark concedes that it had targeted average prices with CVS for 2013 through 2016, it asserts that Relator has not adduced sufficient evidence of the numerical values

of those targets to present to a factfinder, and thus asks that summary judgment be granted in its favor. Relator opposes Caremark's motion and also seeks a summary judgment ruling that her proffered targets for CVS for 2013 through 2016 are correct as a matter of law.

Relator's evidence of Caremark's targeted average prices with CVS includes spreadsheets that associate numbers with "CVS" and "Gen Eff Rate." (Supra § III.D.2(b).) Relator also offers testimony that these spreadsheets tracked the "variance" between Caremark's budgeted target with CVS and actual performance. (See Black 8/18/22 at 103-06.) Moreover, a statement in a Caremark internal slide presentation identified one of these numbers (for 2013) as a "committed rate." (Relator's Ex. 190, CVS-BEHNKE-0276683 at slide 2.) This evidence, if believed by the factfinder, could establish that Relator's proffered rates were the actual targets. Accordingly, Caremark's motion for summary judgment will be denied to the extent it asserts otherwise.

However, Relator has not shown that this evidence is "so powerful that no reasonable jury would be free to disbelieve it," which is the high standard Relator must meet to obtain summary judgment in her favor on an issue on which she bears the burden of proof. <u>Dunkin Donuts Franchising LLC v. Claudia III, LLC</u>, No. 14-cv-2293, 2015 WL 4243534, at *1 (E.D. Pa. July 14, 2015). Caremark has offered possible reasons that a factfinder might doubt the numbers from the spreadsheets, such as the lack of testimony tying specific numbers in Caremark's spreadsheets to budget discussions between Caremark and CVS. For this reason, Relator's motion for partial summary judgment will be denied to the extent it seeks a ruling that Relator's proffered numbers were in fact Caremark's targeted average prices with CVS for 2013 through 2016.

2. <u>2011 through 2012</u>

While Caremark concedes that it had average price targets with CVS for 2013 through 2016, Caremark asserts that no such targets existed in 2011 and 2012, and asks that summary judgment be entered in its favor as to those years.³²

Relator's evidence that Caremark had average pricing targets with CVS in 2011 and 2012 consists, in large part, of a single sentence from a Caremark witness that a target was in effect from "2011 to 2016." (Boratto 10/7/22 at 26:24-27:11.) However, this witness, Eva Boratto, did not agree that Caremark and CVS ever negotiated an average price or that Caremark was ever committed to such a price. Thus, it is unclear that her statement meant that a negotiated, committed rate was in effect in 2011 and 2012. Relator also points to a spreadsheet containing numbers with little context, but does not explain how that spreadsheet shows that Caremark had committed to pay any of the rates that might appear in it. (Relator's Ex. 107.) Caremark counters Boratto's statement with testimony from a CVS in-house attorney that "negotiations" occurred during those years, but that the two sides of the business did not reach "alignment" on a final rate, apparently meaning that no agreement was concluded and Caremark was never committed to pay either side's proposed average. (Bernstein 10/20/22 at 35:23-36:10.)

Relator's evidence is insufficient to raise a dispute of fact as to whether Caremark and CVS had a negotiated average rate in 2011 and 2012. Relator's ambiguous statement from Boratto that a target existed is a "mere ... scintilla" of evidence that would not justify a factfinder in concluding that a negotiated rate reflecting Caremark's actual cost of drugs existed during those years. Anderson, 477 U.S. at 252. Accordingly, summary judgment will be granted to Caremark with regard to CVS in 2011 and 2012.

³² Relator also asserts that a target existed in 2010 but is not seeking damages for that year.

C. Whether Relator Can Prove a False "Claim"

Caremark argues that even if Aetna and SilverScript's price reports were higher, on average, than what Caremark actually spent, Relator still cannot prove her case because she cannot show that any individual "claim" was false. In Caremark's view, it is insufficient to show that prices were inflated "on average," and specific false prices must be identified. Because Relator's expert did not identify specific false prices, only false averages, Caremark asks that summary judgment be granted in its favor.³³

The False Claims Act creates a cause of action against anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). A plaintiff must, therefore, prove "the actual submission of a false claim." <u>United States ex rel. Greenfield v. Medco Health Sols., Inc.</u>, 880 F.3d 89, 98 (3d Cir. 2018). A "claim" is defined, in relevant part, as "any request or demand ... for money or property," subject to certain limitations not at issue here. § 3729(b)(2)(A).

Caremark's argument starts by dividing Relator's general allegation that Caremark overreported drug spending into what Caremark calls a "PDE theory" and a "DIR theory." Caremark asserts that Relator's "PDE theory" is that Caremark's PDE records were false because the prices in them were higher, on average, than Caremark's negotiated average prices. As for the "DIR theory," Caremark posits that Relator's position is that Caremark's DIR reports were false because they did not include price concessions based on guaranteed average prices. Under either theory, Caremark argues that Relator cannot show a false "claim" because she has not identified which

³³ While Relator seeks summary judgment on the element of falsity generally, Relator has not asked for summary judgment on the issue of what constituted an individual false "claim," nor has she asked for summary judgment on the accuracy of her expert's calculations. I therefore only address whether Relator has sufficient evidence to prove the existence of a false claim, not whether a false claim has been established beyond genuine dispute.

specific PDE records and DIR reports reflected prices that were higher than Caremark's negotiated average prices.

Caremark does not identify what it considers to be a "claim" in the context of Medicare Part D, and instead appears to assume that a claim means an individual PDE record or entry in a DIR report. Caremark also does not cite authority on the meaning of "claim," or reference the statutory definition of a "request or demand ... for money," nor does Caremark explain which steps in the Part D price reporting process should be considered "request[s]" or "demand[s]" for subsidies. Caremark also offers no argument for why a "claim" should mean an individual PDE record or DIR report, as opposed to a Part D sponsor's year-end "request" for a subsidy payment based on all its reports for that year. Caremark's briefing is therefore inadequate to "demonstrate[e] the absence of a genuine issue of material fact" on the issue of whether Relator can prove a false "claim." See United States ex rel. Druding v. Care Alternatives, 81 F.4th 361, 375 (3d Cir. 2023) (citing Celotex, 477 U.S. at 323) ("[O]n a motion for summary judgment, it is the moving party who bears the burden of demonstrating the absence of a genuine issue of material fact" (emphasis in original)).

Instead, Caremark cites cases standing for the ordinary proposition that a False Claims Act plaintiff must prove the existence of a false claim. See Greenfield, 880 F.3d at 98; United States ex rel. Quinn v. Omnicare Inc., 382 F.3d 432 (3d Cir. 2004); United States ex rel. Aflatooni v. Kitsap Physicians Serv., 314 F.3d 995 (9th Cir. 2002). For example, Greenfield involved an allegation that the defendant submitted claims for reimbursement to Medicare that falsely certified compliance with the Anti-Kickback Statute. The Third Circuit determined that for a claim to be "false," the "particular patient [must be] exposed to an illegal recommendation or referral," and because the relator could not "demonstrate that any of [the defendant's] ... federally insured

patients viewed" communications related to the alleged kickback, summary judgment was granted to the defendant. <u>Id.</u> at 99-100. That case, like Caremark's other cited cases, therefore stands for the ordinary rule that a plaintiff must prove a false claim, and provides no insight into the level of granularity that this requirement entails.

Here, CMS would make estimated subsidy payments throughout the year and then "reconcile" (correct) those payments at the end based on all reports submitted to date, through CMS's "Payment Reconciliation System." CMS made these payments "in the aggregate," rather than as separate payments for each PDE record and DIR report. (Supra § III.B.5.) Relator's expert testimony, if believed, could show that Aetna and SilverScript requested subsidies based on drug spending that was higher than Caremark's negotiated average prices with pharmacies, leading Aetna and SilverScript to request higher subsidies than they were owed in the year-end reconciliation. (Supra § III.F.2.) Caremark has failed to explain why such evidence would be insufficient for a factfinder to conclude that Caremark caused Aetna and SilverScript to make false demands for Part D subsidies that constituted false "claims." Analogously, in United States v. Krizek, 192 F.3d 1024 (D.C. Cir. 1999), the Government was permitted to prove that medical bills were false based on listed services totaling more than 24 hours in a day, even if this methodology did not reveal which fictitious services pushed the total over the 24-hour mark. Id. at 1030. Caremark's motion for summary judgment will therefore be denied on the issue of whether Relator can prove a false claim.

Caremark makes a similar argument that Relator cannot prove damages because her expert's calculations do not attribute CMS's alleged overpayments to specific PDE records and DIR reports. The False Claims Act permits the Government to recover, among other penalties, "3 times the amount of damages which the Government sustains because of" the submission of a false claim.

31 U.S.C. § 3729(a)(1). Such damages are measured "by the amount of money the government paid by reason of the false statement above what it would have paid absent the false statement."

U.S. ex rel. Harrison v. Westinghouse Savannah River Co., 352 F.3d 908, 922 (4th Cir. 2003). Relator's expert's calculations, if believed by the factfinder, could show that CMS paid Caremark's clients higher subsidies than the ones to which they were entitled based on Caremark's true prices with pharmacies. (Supra § III.G.) Caremark has not identified a requirement, either under the False Claims Act or Medicare Part D, to allocate damages to individual PDE records or DIR reports, particularly given the evidence that CMS made subsidy payments on an aggregate basis. (Supra § III.B.5.) In addition, while Caremark's expert faults Relator's expert for allocating price concessions to Part D plans whose individual sale prices were lower than Caremark's guaranteed average prices, Caremark has not cited authority that such an allocation would have been inconsistent with CMS's reporting rules, which permitted some kinds of allocation. (See Caremark's Ex. 57, 2011 DIR Reporting Requirements § III.A.) Caremark's motion for summary judgment will therefore be denied as to damages.

D. Materiality

A plaintiff under the False Claims Act must prove that any alleged misrepresentations were "material to the Government's payment decision." <u>Universal Health Servs.</u>, <u>Inc. v. United States ex rel. Escobar</u>, 579 U.S. 176, 192 (2016). Both parties seek summary judgment in their favor on this element.

Materiality is statutorily defined as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). This standard "looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." Escobar, 579 U.S. at 193 (alteration omitted). It is a "demanding" standard that requires a falsity that is more than "minor or insubstantial," and is not met merely because a "condition of

payment" has been violated that would give the government "the option to decline to pay if it knew of the defendant's noncompliance." <u>Id.</u> at 194. However, that a condition of payment has been violated is still "relevant" to the materiality inquiry, and evidence that the Government continued to pay despite knowledge of a violation is "strong evidence that the requirement[] [was] not material." <u>Id.</u> at 195.

A critical aspect of Caremark's materiality argument is the distinction between materiality of the "claim" and materiality of the "misrepresentation," with Relator's obligation being to prove the latter. It appears to be undisputed that Aetna and SilverScript's claims for Part D subsidies were material in the sense that CMS would not have paid if the claims were not submitted, or that CMS would have paid less had Aetna and SilverScript requested less. But Caremark argues more is required—namely, that CMS would have declined to pay subsidies had it known of the "specific ... falsehoods" regarding Caremark's negotiated average prices. (ECF No. 294 at 245.) To do otherwise, Caremark insists, would "conflate[] materiality with causation," in that any false claim would be automatically material on the theory that, had the defendant not submitted the claim, the Government would not have paid. United States ex rel. Freedman v. Bayada Home Health Care, Inc., No. 19-cv-18753, 2021 WL 1904735, at *8 (D.N.J. May 12, 2021). Caremark's rule finds support in the language of Escobar that materiality looks to the "effect on the likely or actual behavior of the recipient of the alleged misrepresentation," rather than of the claim as a whole. 579 U.S. at 193. It is true, as Caremark points out, that materiality and causation are separate elements under the False Claims Act, meaning not any false claim that causes the Government to overpay is automatically material. Freedman, 2021 WL 1904735, at *8; see also United States ex rel. Streck v. Takeda Pharms. Am., Inc., No. 14-cv-9412, 2022 WL 595308, at *15 (N.D. Ill. Feb. 28, 2022) ("Relator must prove more than a difference in payment to show materiality under the False Claims

Act."). Finally, Relator does not disagree with Caremark's proposed standard in her reply brief. Accordingly, I accept Caremark's standard for materiality, and conclude that Relator must establish that had CMS known of Caremark's guaranteed average pricing terms and the corresponding mismatch with reported prices, such knowledge would have had a "likely" "effect" on CMS's payment decisions. Escobar, 579 U.S. at 193.

To meet this standard, Relator principally relies on the fact that CMS used reported prices to calculate subsidies, and, according to Relator's expert, Caremark's false reports caused CMS to pay too much—hundreds of millions of dollars too much. (Relator's Facts ¶ 20.) In Relator's view, an inference follows that CMS would not "willingly pay inflated expenses." <u>United States ex rel.</u> <u>Grubea v. Rosicki, Rosicki & Assocs., P.C.</u>, 318 F. Supp. 3d 680, 702 (S.D.N.Y. 2018). Relator also points out that CMS conditioned subsidy payments on price reports, required both Part D sponsors and their PBMs to certify the accuracy of their data, and told industry participants that failing to disclose price concessions would be an example of fraud. (Supra § III.B.4.)

Caremark responds with what it views as CMS's actual conduct in the face of information suggesting Caremark had negotiated average prices with pharmacies. Caremark points to CMS's discussions with Caremark's David Azzolina, in particular Azzolina's May 26, 2016 email stating that Caremark had average pricing terms with "a few pharmacies" "across the pharmacy book of business." (Supra § III.K.) As far as the summary judgment record reveals, CMS never accused Caremark, Aetna, or SilverScript of wrongdoing with respect to those average pricing terms, and Caremark insists this is "strong evidence" that CMS did not view any problems as material. Escobar, 579 U.S. at 195. Caremark also references what it contends was CMS's general knowledge

that average pricing terms were used in the industry and its failure to update its regulations to specify that a guaranteed average price was the actual price of drugs. (Supra § III.K.3.)³⁴

I conclude that factual disputes preclude summary judgment to either party on the issue of materiality. A factfinder could accept Relator's evidence that Caremark's misrepresentations cost the government hundreds of millions of dollars in Medicare Part D subsidies. Since Medicare Part D is a program that primarily exists to fund the cost of drugs for older Americans, a factfinder could view misrepresenting drug prices as going to the "essence of the bargain." See Escobar, 579 U.S. at 193 n.5. And Caremark's evidence that CMS became aware of Caremark's pricing practices is not conclusive: for example, a factfinder might disagree that Caremark's reference to "a few pharmacies" adequately apprised CMS of the scale of the situation, given that those pharmacies were CVS, Rite Aid, and Walgreens. And even if Caremark is correct that the phrase "across the pharmacy book of business" would have alerted CMS that Caremark's average pricing applied to both Part D and commercial purchases, it does not necessarily follow that CMS would understand that above-average payments on Part D purchases could be used to offset below-average payments on commercial purchases. Moreover, it is not indisputable that CMS would have appreciated Azzolina's email to mean that Caremark's price reports omitted average pricing terms. While Caremark points to the sentence "The [guaranteed average] is also not associated with additional arrangements that reduce the price, such as DIR arrangements with pharmacies where there may be an agreed upon incentive payment and/or discount based on pharmacy performance,"

³⁴ The Government filed a "statement of interest" in connection with the present summary judgment briefing. (ECF No. 312.) Although the Government's statement asserts generally that it "relies on accurate reporting of Medicare Part D drug price information," it has not taken a position on whether Caremark's alleged misrepresentations were material.

the word "additional," as well as the example given, could suggest that Caremark was not disavowing that the average price itself might be reportable as a price concession.

It is true that the Government would have learned of Relator's <u>allegations</u> of fraud when she filed her complaint under seal in 2014, and that Caremark continued to report individual sale prices with respect to CVS in 2015 and 2016, apparently without challenge from CMS. (<u>Supra</u> § III.K.4.) But a factfinder would be entitled to weigh this evidence against Relator's evidence of materiality, including her evidence that misrepresenting drug prices went to the heart of the Medicare Part D program. Government inaction in the face of alleged fraud is "not dispositive ... evidence of immateriality," particularly given that "awareness of allegations of fraud" is not the same as "'actual knowledge' that fraud occurred," and the Government may have reasons not to "prematurely end a relationship with a contractor over unproven allegations." <u>United States ex rel. Druding v. Care Alternatives</u>, 81 F.4th 361, 375 (3d Cir. 2023).³⁵

But while Relator's evidence of materiality is sufficient at this stage of the proceedings, it is also not conclusive. A factfinder could believe Caremark that it told CMS about its pricing and CMS took no action. That would be "strong evidence" that the information was "not material." Escobar, 579 U.S. at 195. I also note that Relator has not sought summary judgment on her expert's damages calculations, and I therefore cannot say that a factfinder would be required to accept that

³⁵ Caremark extensively relies on <u>United States ex rel. Spay v. CVS Caremark Corp.</u>, 875 F.3d 746 (3d Cir. 2017), but the facts of that case are unlike those here. In <u>Spay</u>, the alleged false claims were for real prescriptions at real prices, and the only alleged defect was that Caremark had worked around a technical limitation in the data by substituting a "dummy prescriber ID." <u>Id.</u> at 750. There was, accordingly, "no question that '[t]he claims themselves were neither false nor fraudulent' and that CMS accepted this 'workaround' as a 'technical, formulaic way of preventing a computer program from denying legitimate claims.'" <u>Druding</u>, 81 F.4th at 373. Here, by contrast, a factfinder could accept Relator's argument that misrepresenting <u>prices</u>, unlike prescriber IDs, went to the heart of the Part D program.

Caremark's false reports led to hundreds of millions of dollars in excess spending. If the effect were "minor or insubstantial," that could mean it was not material. Id. at 194.

For these reasons, summary judgment will be denied to both parties on the issue of materiality.

E. Causing the Submission of False Claims

Relator alleges that Caremark caused the submission of false claims on behalf of other entities, Aetna and SilverScript, and has moved for summary judgment on the question of whether Caremark caused these entities to submit false claims. Caremark has not moved for summary judgment on this issue.³⁶

The False Claims Act reaches any person who "causes to be presented[] a false or fraudulent claim for payment." 31 U.S.C. § 3729(a)(1)(A). The causation element entails "ordinary [proximate] causation principles from negligence law," which, in turn, ask whether the defendant's conduct was a "substantial factor" in causing the submission of a false claim. <u>United States ex rel. Schmidt v. Zimmer, Inc.</u>, 386 F.3d 235, 244 (3d Cir. 2004). "[T]o say that one event was a proximate cause of another means that it was not just any cause, but one with a sufficient connection to the result." <u>Paroline v. United States</u>, 572 U.S. 434, 444 (2014). This is a "flexible concept" that "defies easy summary," but generally requires a "direct relation between the injury asserted and the injurious conduct alleged." <u>Id.</u> (quotation marks omitted).

Here, Caremark does not dispute that it provided information to Aetna and SilverScript that those entities then used to submit drug price reports. Instead, Caremark argues that a factual question exists as to proximate cause because Aetna and SilverScript exercised independent judgment

³⁶ Relator has not moved for summary judgment on the issue of whether Aetna and SilverScript's reports caused CMS to overpay.

over their reports, interposing a superseding cause that broke the proximate causal chain. In making this argument, Caremark emphasizes that the ultimate responsibility for submitting price reports (both contractual and regulatory) was on Part D sponsors, not PBMs.

In analyzing whether an intervening act defeats proximate cause, the usual rule from tort law is that "the 'intervention of a force which is a normal consequence of a situation created by the actor's ... conduct is not a superseding cause of harm which such conduct has been a substantial factor in bringing about.'" <u>United States ex rel. Schmidt v. Zimmer, Inc.</u>, 386 F.3d 235, 244 (3d Cir. 2004) (quoting Restatement (Second) of Torts § 443). Thus, if the filing of a false claim was the "normal consequence" of a defendant's conduct, the defendant may be found to have "caused" the filing even if another party "made its own decision to file [the] false certification." <u>Id.</u>³⁷

Relator's argument is that Caremark played a "pivotal" role in its clients' price reporting, and only Caremark had the necessary information to report accurate prices to CMS—namely, Caremark's average pricing rates with pharmacies. As to Aetna, Relator describes how Caremark provided Aetna "instructions" on how to "calculate the dollar amount to be paid to the pharmacy," which were then "implemented" "in an automated fashion" on Aetna's insurance claims adjudication system, to create price reports that were sent to CMS. (Supra § III.H.) In response, Caremark offers the history of its interactions with Aetna, in which Aetna was informed that Caremark had average pricing guarantees with pharmacies that differed from individual sale prices. Caremark does not allege that Aetna ever learned what those average prices were such that Aetna could have

³⁷ Neither party addresses the burden of proof on the foreseeability of an intervening cause. I will therefore assume, for purposes of summary judgment only, that Relator must carry the usual burden of proving each element of her claims, including that there was an unbroken causal chain.

reported those prices to CMS. But Caremark nonetheless contends that Aetna could have decided that continuing to report individual sale prices was noncompliant with CMS regulations.³⁸

These facts are not sufficiently clear to warrant granting summary judgment in Relator's favor as to Aetna. Relator's briefing does not explain what it meant for Aetna to "implement" Caremark's "instructions" on its "system," and her argument is simply too sparse to show that these facts render the element of causation satisfied beyond genuine dispute. Because it is not clear from Relator's statement of facts that Caremark provided price reports to Aetna with the intention that they be forwarded to CMS unmodified, a factfinder could disagree with Relator that the "normal consequence" of Caremark's conduct was the submission of false claims.

As for SilverScript, it is undisputed that Caremark itself: (1) submitted PDE records on SilverScript's behalf, (2) provided SilverScript draft DIR reports in a "CMS-ready format," and (3) certified to SilverScript that these reports included all reportable price concessions. Caremark also certified the accuracy of SilverScript's reports directly to CMS. (Supra § III.H.) These facts leave no room for genuine dispute that the "normal consequence" of Caremark's actions was that SilverScript would submit price reports listing individual sale prices rather than guaranteed average prices, which were false. Caremark controlled all information that would go into SilverScript's price reports, and represented to both SilverScript and CMS that such information was complete and accurate. Even if SilverScript theoretically could have prevented Caremark from submitting these reports (and Caremark offers no evidence that it could), there can be no genuine dispute that the "normal consequence," or at least a normal consequence, was that SilverScript would allow Caremark to submit the reports that Caremark had certified were accurate.

³⁸ Relator disputes the admissibility of documents produced as part of Aetna's outside-counsel investigation into Caremark's pricing. Because I conclude that these documents do not alter the outcome at summary judgment, I need not address their admissibility.

Caremark argues that the causal chain could nevertheless be broken because SilverScript was required to "evaluate independently" submitted information, relying on In re Plavix Mktg., Sales Pracs. & Prod. Liab. Litig., 123 F. Supp. 3d 584, 612 (D.N.J. 2015). However, Plavix does not stand for the proposition that an independent evaluation breaks the causal chain when the "normal consequence" test is otherwise satisfied. Instead, Plavix involved an allegation that a pharmaceutical manufacturer falsely marketed its drug, causing that drug to be listed on Medicaid's formulary, resulting in false claims when physicians prescribed that drug and sought Medicaid reimbursement. The defendant argued that the requests for reimbursement were not false because Medicaid committees were required to "evaluate independently" the clinical data related to the drug before placing it on the formulary. See id. at 612. However, the court did not render a decision on that basis. Rather, it determined that reimbursement requests were not false because they truthfully represented that the drug was on the formulary. Id. Therefore, Plavix is not a case about proximate causation.

Caremark also points to <u>United States v. Teva Pharms. USA, Inc.</u>, No. 13-cv-3702, 2019 WL 1245656 (S.D.N.Y. Feb. 27, 2019). Although <u>Teva</u> was a False Claims Act case, its discussion of causation pertained to an embedded issue under the Anti-Kickback Statute—namely, whether patients were "exposed" to certain alleged kickbacks. <u>Id.</u> at *24. The court speculated (not as part of its ruling) that prescribing physicians' independent judgment might have prevented patients from being exposed to kickbacks. <u>Id.</u> at *27. That case therefore does not bear on what constitutes proximate cause under the False Claims Act. Summary judgment will be granted to Relator on the issue of whether Caremark caused SilverScript's reports.

For these reasons, summary judgment will be granted to Relator on causation as to Silver-Script, but denied as to Aetna.

F. Scienter

Caremark has moved for summary judgment on scienter. To show liability under the False Claims Act, a plaintiff must prove that the defendant "knowingly" presented a false claim to the government, an element known as "scienter." 31 U.S.C. § 3729(a)(1)(A). The statute defines "knowingly" to include "actual knowledge," "deliberate ignorance," and "reckless disregard," and clarifies that specific intent to defraud is not required. § 3972(b)(1)(A), (B). This is a "subjective" standard that looks to the defendant's actual knowledge and beliefs, not those of a hypothetical, reasonable person in like circumstances. <u>United States ex rel. Schutte v. SuperValu Inc.</u>, 598 U.S. 739, 749 (2023).

Here, Caremark does not dispute that it knew it had average pricing terms with certain pharmacies, that it knew the negotiated averages differed from individual sale prices, or that it knew its clients reported only individual sale prices as the cost of drugs. That is, Caremark makes no assertion that it lacked knowledge of the facts that caused its price reports to be out of compliance with CMS's regulations as I have interpreted them. Instead, the only dispute regarding scienter is whether Caremark subjectively understood what CMS's regulations required—namely, that they mandated reporting guaranteed average prices under the circumstances present here.

Where a claim under the False Claims Act alleges a defendant's violation of a legal requirement, scienter turns on the defendant's subjective understanding of what the law demanded. Schutte, 598 U.S. at 752. Thus, if Caremark were innocently unaware that CMS's regulations required it to report the guaranteed average price as the actual price of drugs, Caremark would lack scienter. On the other hand, if Caremark knew, deliberately ignored, or recklessly disregarded that average price reporting was required, scienter would be met. See id.

Caremark argues that Relator lacks sufficient evidence to prove scienter, such that summary judgment should be granted in its favor. As support, Caremark notes that throughout the time

period underlying this regulation, its stated interpretation of CMS's regulations remained constant, suggesting this belief was honestly held. For example, when Aetna and CMS pressed for information about Caremark's average pricing terms, Caremark responded each time that only its individual sale prices counted as the price of drugs. Caremark further points out that even under Relator's theory of the case, Caremark only committed the alleged "fraud" about half the time it had an opportunity to do so, which in Caremark's view suggests that any mismatch in price reporting occurred through happenstance rather than a deliberate scheme to mislead. Finally, Caremark insists that its price reporting always conformed to industry practice, meaning Caremark had no reason to suspect that its interpretation of CMS's regulations might be off the mark.

Relator responds with various facts that she claims show conscious wrongdoing. The bulk of Relator's evidence consists of documents and testimony showing that Caremark understood it was earning margin or "spread" on purchases for Part D plans. This evidence includes Caremark employee Allison Brown's alleged statement that there was a "see-saw" effect between Part D and commercial prices, Caremark's offer to negotiate better prices with pharmacies and share only some of the benefit with Aetna, Caremark's internal documents discussing "value" obtained from Part D purchases, and Caremark's contracting strategy targeting the value it would earn from guaranteed average pricing terms with pharmacies. (Supra § III.I.) While Relator does not allege that earning margin on Part D purchases was illegal per se, Relator argues Caremark must have understood that the prices it was charging clients and telling clients to report to CMS included some cost for PBM services, contrary to CMS's instructions that PBM services were excluded from Part D subsidies.

Next, Relator points to Caremark's "reconciliation" spreadsheets, which contained calculations showing what Caremark was obligated to pay pharmacies under guaranteed average pricing

terms. These spreadsheets reported separate totals for Part D and commercial purchases. (<u>E.g.</u>, Relator's Ex. 68.) While the numbers are not easy for a layperson to interpret, Relator argues that any reader experienced in the insurance business would understand a simple mathematical fact: higher-than-average payments on Part D purchases reduced what Caremark otherwise owed due to its lower-than-average payments on commercial purchases. In Relator's view, this was plainly a type of discount, and Caremark would have understood that it had to be reported as such.

Relator also notes that an internal Caremark slide presentation stated that clients could view the mismatch between guaranteed average prices and individual sale prices as a "problem." (Relator's Ex. 260 at slide 27.) While the "problem" likely meant a competitive advantage problem rather than a compliance problem, Relator insists that the point still stands that Caremark was subjectively aware that others might view guaranteed average prices as the "real" prices. That interpretation is corroborated by the alleged statement of Allison Brown that Caremark "ha[d] better deals" than the ones it "pass[ed] ... along to" Aetna—implying, in Relator's view, that Caremark understood it was "really" paying guaranteed average prices and not individual sale prices. (Behnke 6/30/22 at 282:14-17.) Similarly, Relator argues that internal Caremark documents on "restated margin" reflected an understanding that individual sale prices did not accurately reflect the cost of drugs, and even Caremark internally realized it had to alter those prices to convey the true value of its pharmacy contracts. (Relator's Ex. 265.)

Finally, Relator asserts that Caremark exhibited a lack of candor with CMS when questioned about its average pricing terms, suggesting, in Relator's view, an awareness that the truth was inculpatory. Relator points out that Caremark referred to the three major pharmacy chains CVS, Walgreens, and Rite Aid as "a few pharmacies," and failed to mention that Caremark's

average pricing terms allowed it to undershoot the target on commercial purchases so long as it overshot on Part D purchases. (Relator's Ex. 26 at CVS-BEHNKE-1830849.)

Relator does not have a "smoking gun" document from Caremark admitting to (or even acknowledging the possibility of) an interpretation of CMS's regulations at variance with Caremark's own. Relator also does not argue that Caremark's false reporting was motivated by a desire to obtain increased Part D subsidies for its clients, and the parties' summary judgment briefing does not discuss whether Caremark received any share of the subsidies that its reporting allegedly inflated. Relator thus does not allege that Caremark stood to profit by causing its clients to receive too-high subsidies from CMS. Instead, Relator's theory is that Caremark sought to earn greater "spread" on commercial purchases by shifting those costs to Part D purchases. Relator does not allege that earning spread was inherently illegal, though she does suggest it was contractually improper. Thus, while Relator's theory of damages focuses on subsidies paid to Caremark's Part D clients, Relator appears to view these damages as a side-effect of a scheme that was really aimed at charging those same clients more than Caremark was contractually allowed to charge.

Nevertheless, a factfinder could infer from Relator's evidence that Caremark had a sufficient understanding of CMS's price reporting requirements to meet the standard for scienter under the False Claims Act. CMS's regulations specified that Part D sponsors were supposed to report "actually paid" prices, and a factfinder could view Caremark's statements to Aetna and internal documents as reflecting an understanding that its negotiated average prices were what it "actually paid." It would not be unreasonable for a factfinder to conclude from this evidence that the element of scienter is met.

Caremark's contrary evidence creates at most a factual dispute. For example, while a factfinder could agree with Caremark on the implausibility of carrying out a fraudulent scheme only haphazardly and less than half the time, a factfinder might nevertheless believe that Caremark at least recklessly disregarded the risk that continuing to report only individual sale prices in the years when the guaranteed average price dipped below them could run afoul of CMS's requirements. Similarly, while it might not be unreasonable to credit Caremark's experts that reporting only individual sale prices was industry standard, a factfinder could equally well discredit such testimony based on the lack of examples of other Part D sponsors or PBMs who reported prices in the same way as Caremark. Or, a factfinder might be convinced that the meaning of the regulations was sufficiently clear that Caremark should have deviated from the alleged industry custom in order to remain compliant. Finally, a factfinder might reject Caremark's position that it consistently interpreted CMS's regulations as to require only the reporting of individual sale prices if the factfinder were convinced that the requirement to report "actually paid" prices was clear and Caremark would have understood it.

For these reasons, Caremark's motion for summary judgment as to scienter will be denied.

VI. <u>CONCLUSION</u>

For the reasons set out above, the parties' motions for summary judgment will be denied, except in the following respects: (1) Caremark's motion for summary judgment will be granted as to Caremark's payments to CVS in 2011 and 2012; (2) Relator's motion for partial summary judgment will be granted on the issue of falsity; and (3) Relator's motion will be granted on the issue of whether Caremark caused SilverScript to submit the price reports that it did.

An appropriate order follows.